

EXHIBIT 21

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION REPORT

DIGOXIN TABLETS, 0.125 mg
1,600,000 TABLETS

BATCHES 4318A, 4320A, and 4322A

MPR NO. 14502

Revision No. 00

Prepared by: *[Signature]*

Date Prepared: 12/23/94

Approved by:

[Signature]

Quality Assurance Director

Date: 12/29/94

[Signature]

Manufacturing Operations Director

Date: 12/29/94

[Signature]

Regulatory Affairs Director

Date: 12/28/94

[Signature]

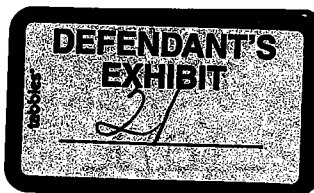
Quality Control Director

Date: 12/27/94

[Signature]

VP Operations

Date: 12-27-94



AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION SUMMARY

| | | | |
|---------|---------------------------|-------|-------|
| PRODUCT | DIGOXIN TABLETS, 0.125 mg | BATCH | 4318A |
| | | | 4320A |
| | | | 4322A |

The following comments apply to the three 1,600,000 tablet validation batches produced in this series.

This report includes data through Compression, which is the finished dosage form.

The process used to produce this batch follows exactly that shown in the normal batch record. Copies of the actual batch records are available in the file.

The data supporting the validation of the analytical methods used may be found in the Analytical Method Validation Report issued for this product.

A copy of the protocol to be followed for this project is included.

Evaluation of the data includes calculation of the Process Capability Index, Cp, when appropriate. Cp is a measure of the ability of a process to produce material that is all within the specification range. It verifies that the entire distribution curve for the data collected falls within the allowable limits. The following equation is used.

$$Cp = \frac{(\text{Upper Limit} - \text{Lower Limit})}{6 \times \text{St. Dev.}}$$

Any value equal to or greater than 1 is acceptable.

**AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION**

DIGOXIN TABLETS, 0.125 mg MPR NO. 14502 - 00

CONCLUSIONS AND OBSERVATIONS

All samples met the established acceptance criteria.

Based on these three batches, the process is considered validated and is acceptable for use.

The data verifies the initial acceptance criteria for all parameters. At this point no revision to any of these ranges will be made.

The final blends showed adequate uniformity for all batches. The resulting Cp value is 2.9, which is more than acceptable.

Content uniformity results are all within the acceptance criteria, and are essentially comparable to the blend results.

Results for both the final blends and content uniformity center around the label amount.

All Dissolution samples for the three batches met the USP requirements. The values for the three batches are comparable, however there is some variability within the individual batches.

The data for each protocol step follows a summary of that step, in the order in which it appears in the protocol.

Amide Pharmaceutical, Inc.

Process Validation

DIGOXIN TABLETS, 0.125 mg

Process Validation Summary

Batch Size - 1,600,000 Tablets

| Test | Initial Limits | Batch | 4318A | 4320A | 4322A | Combined | Final Limits |
|--|----------------------------------|---------|-------|-------|-------|----------|----------------------------------|
| Final Blend Assay (%) | 85.0 - 115.0 %Th. (Ind.) | Average | 98.5 | 98.8 | 98.3 | 98.5 | 85.0 - 115.0 %Th. (Ind.) |
| | | Std Dev | 1.0 | 1.5 | 1.0 | 1.1 | |
| | | Cp | | | | 2.9 | |
| Compression Weight (g) | 0.097 - 0.113 g | Average | 0.105 | 0.105 | 0.105 | 0.105 | 0.097 - 0.113 g |
| | | Std Dev | 0.002 | 0.002 | 0.002 | 0.002 | |
| | | Cp | | | | 1.5 | |
| Compression Hardness (Kp) | 1.0 - 6.0 kp | Average | 4.5 | 4.5 | 4.6 | 4.5 | 1.0 - 6.0 kp |
| | | Std Dev | 0.4 | 0.4 | 0.4 | 0.4 | |
| | | Cp | | | | 2.2 | |
| Compression Thickness (mm) | 2.0 - 3.0 mm | Average | 2.63 | 2.62 | 2.62 | 2.62 | 2.0 - 3.0 mm |
| | | Std Dev | 0.03 | 0.03 | 0.03 | 0.03 | |
| | | Cp | | | | 5.7 | |
| Compression Friability (%) | NMT: 1.0 % | Average | 0.09 | 0.08 | 0.08 | 0.08 | NMT: 1.0 % |
| | | Std Dev | 0.03 | 0.03 | 0.03 | 0.03 | |
| Compression Disintegration (min) | N/A | Average | 3.2 | 3.3 | 3.3 | 3.3 | N/A |
| | | Std Dev | 0.4 | 0.5 | 0.5 | 0.5 | |
| Compression Content Uniformity (%) | 85.0 - 115.0 % RSD NMT: 6.0 % | Average | 101.3 | 100.4 | 101.3 | 101.0 | 85.0 - 115.0 % RSD NMT: 6.0 % |
| | | Std Dev | 1.1 | 1.7 | 1.7 | 1.6 | |
| | | Cp | | | | 3.2 | |
| Compression Dissolution (%) 15 min. | NMT: 90% (ind.) | Average | 83.0 | 85.0 | 81.4 | 83.1 | NMT: 90% (ind.) |
| | | Std Dev | 2.2 | 2.1 | 2.5 | 2.7 | |
| Compression Dissolution (%) 60 min. | NLT: 80% (avg) | Average | 97.2 | 99.7 | 97.2 | 98.0 | NLT: 80% (avg) |
| | | Std Dev | 2.3 | 3.2 | 3.1 | 3.1 | |

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg MPR NO. 14502 - 00

PROTOCOL STEP - RAW MATERIALS

The raw materials used will be tested, as stated in the protocol, in accordance with approved specifications and methods. In addition, bulk density, tamped density and particle size distribution will be included.

ACCEPTANCE CRITERIA

Parameters normally evaluated will be compared to the current specifications. The density and particle size data will be gathered and used to formulate guidelines when sufficient data is accumulated.

RESULTS - See attached data summary sheets.

CONCLUSIONS AND COMMENTS

All data is acceptable.

Any differences noted do not appear to have any effect on finished product quality.

Particle size determinations were run on two different pieces of equipment. One is a "Ro-Tap" type unit and the other a Micron Air Jet Sieve. For samples run on the "Ro-Tap" the coarser mesh screen is listed first.

It should be noted that particle size and density evaluation was not done for the Yellow Lake Blend. Since this material is present in such a small amount any differences in either of these parameters will have no significant effect on the final blend.

The particle size distribution for Digoxin P.O. No. 2629-1 was run on the "Ro-Tap" type shaker. That for P.O. No. 3929 was run on the Micron Air Jet Sieve. The results obtained on the two units differed significantly. Due to the fact the the two units employ different technologies no comparison will be made. It should be noted that no effect on content uniformity or dissolution was observed.

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Raw Material Usage Chart

| Item # | Item Name | Batch # 4318A P.O. # | Batch # 4320A P.O. # | Batch # 4322A P.O. # |
|--------|-------------------------------------|-------------------------|-------------------------|-------------------------|
| 3115 | Corn Starch, NF | 4025 | 4025 | 4025 |
| 0111 | Digoxin, USP | 2629-1 | 2629-1 & 3929 | 3929 |
| 3044 | D&C Yellow #10 Aluminum Lake 15-20% | 3844 | 3844 | 3844 |
| 3000 | Croscarmellose Sodium, NF | 4026 | 4026 | 4026 |
| 3051 | Lactose Hydrous Impalpable, NF | 4028-1 | 4028-1 | 4028-1 |
| 3088 | Starch Pregelatinized, NF | 4027 | 4027 | 4027 |
| 3059 | Microcrystalline Cellulose, NF | 4023 | 4023 | 4023 |
| 3050 | Lactose Anhydrous, NF | 4015 | 4015 | 4015 |
| 3089 | Stearic Acid, NF | 3910 | 3910 | 3910 |
| 3081 | Silicon Dioxide, NF | 3696 | 3696 | 3696 |

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION*****DIGOXIN TABLETS, 0.125 mg***

Raw Material Comparison - Corn Starch, NF (3115)

| | |
|--------------------|------------------------|
| P.O. # | 4025 |
| Test Type | Initial |
| Manufacturer | National Starch & Chem |
| Manufacturer Lot # | HD-6628 |

| PARAMETERS | SPECIFICATIONS | |
|------------------------|----------------|-----------|
| DESCRIPTION | Passes Test | Passes |
| IDENTIFICATION A | Positive | Passes |
| IDENTIFICATION B | Positive | Passes |
| MICROBIAL LIMITS | Passes Test | Passes |
| PH | 4.5 - 7.0 | 5.7 |
| LOSS ON DRYING | NMT 14.0% | 2.1% |
| RESIDUE ON IGNITION | NMT 0.5% | 0.1% |
| IRON | NMT 0.002% | < 0.002% |
| OXIDIZING SUBSTANCES | Passes Test | Passes |
| SULFUR DIOXIDE | Passes Test | Passes |
| BULK DENSITY | | 0.52 g/mL |
| TAP DENSITY | | 0.72 g/mL |
| PARTICAL SIZE (US 325) | % Retained | 3.9% |
| PARTICAL SIZE (US 200) | % Retained | 2.6% |
| PARTICAL SIZE (US 100) | % Retained | NIL |

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Raw Material Comparison - Digoxin USP (0111)

| | | |
|--------------------|----------------------|----------------------|
| P.O.# | 2629-1 | 3929 |
| Test Type | Initial | Initial |
| Manufacturer | Boehringer Ingelheim | Boehringer Ingelheim |
| Manufacturer Lot # | 240180 | 240254 |

| PARAMETERS | SPECIFICATIONS | RESULTS | RESULTS |
|------------------------|----------------|-----------|-----------|
| DESCRIPTION | Passes Test | Passes | Passes |
| IDENTIFICATION A | Positive | Passes | Passes |
| IDENTIFICATION B | Positive | Passes | Passes |
| IDENTIFICATION C | Positive | Passes | Passes |
| LOSS ON DRYING | NMT 1.0% | 0.6% | 0.7% |
| RESIDUE ON IGNITION | NMT 0.5% | 0.1% | 0.1% |
| RELATED GLYCOSIDES | NMT 3% | < 3% | < 3% |
| ASSAY | 95.0 - 101.0% | 98.6% | 98.6% |
| BULK DENSITY | | 0.24 g/ml | 0.23 g/ml |
| TAP DENSITY | | 0.37 g/ml | 0.36 g/ml |
| PARTICLE SIZE (US 200) | % Retained | 95.6% | N11 |
| PARTICLE SIZE (US 325) | % Retained | 4.0% | 6.1% |

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Raw Material Comparison - D&C Yellow #10 Aluminum Lake 15-20% (3044)

| | |
|--------------------|----------|
| P.O. # | 3844 |
| Test Type | Initial |
| Manufacturer | Colorcon |
| Manufacturer Lot # | Aa-7934 |

| PARAMETERS | SPECIFICATIONS | RESULTS |
|----------------|----------------|---------|
| DESCRIPTION | Passes Test | Passes |
| IDENTIFICATION | Positive | Passes |
| Loss on Drying | N/A | 15.4% |

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION*****DIGOXIN TABLETS, 0.125 mg***

Raw Material Comparison - Croscarmellose Sodium, NF (3000)

| | |
|--------------------|---------|
| P.O. # | 4026 |
| Test Type | Initial |
| Manufacturer | FMC |
| Manufacturer Lot # | T434N |

| PARAMETERS | SPECIFICATIONS | RESULTS |
|---|-------------------|-----------|
| DESCRIPTION | Passes Test | Passes |
| IDENTIFICATION A | Positive | Passes |
| IDENTIFICATION B | Positive | Passes |
| IDENTIFICATION C | Positive | Passes |
| pH | 5.0 - 7.0 | 6.5 |
| LOSS ON DRYING | NMT 10.0% | 2.5% |
| HEAVY METALS | NMT 0.001% | < 0.001% |
| SODIUM CHLORIDE & SODIUM STARCH GLYCOLATE | NMT 0.5% | 0.21% |
| DEGREE OF SUBSTITUTION | 0.60 to 0.85 | 0.69 |
| CONTENT OF WATER SOLUBLE MATERIAL | 1.0% - 10.0% | 3.2% |
| SETTLING VOLUME | 10.0 mL - 30.0 mL | 22 mL |
| MICROBIAL TEST | | Passes |
| BULK DENSITY | | 0.50 g/mL |
| TAP DENSITY | | 0.72 g/mL |
| PARTICLE SIZE (US 325) | % Retained | 5.7% |
| PARTICLE SIZE (US 200) | % Retained | 0.9% |

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Raw Material Comparison - Lactose Hydrous Impalpable NF (3051)

| | |
|--------------------|--------------|
| P.O. # | 4028-1 |
| Test Type | Initial |
| Manufacturer | HMS Chemical |
| Manufacturer Lot # | 034/435 |

| PARAMETERS | SPECIFICATIONS | RESULTS |
|--------------------------------|-------------------|-----------|
| DESCRIPTION | Passes Test | Passes |
| IDENTIFICATION A | Positive | Passes |
| IDENTIFICATION B | Positive | Passes |
| CLARITY AND COLOR OF SOLUTION | Passes Test | Passes |
| LOSS ON DRYING | NMT 1.0% | 0.3% |
| SPECIFIC ROTATION | +54.8° to +55.5° | +55.3° |
| MICROBIAL LIMITS | Passes Test | Passes |
| WATER | Hydrous: NMT 5.5% | 5.1% |
| RESIDUE ON IGNITION | NMT 0.1% | 0.03% |
| HEAVY METALS | NMT 5 ppm | < 5 ppm |
| ACIDITY/ALKALINITY | Passes Test | Passes |
| PROTEIN/LIGHT ABSORBING IMPUR. | Passes Test | Passes |
| ORGANIC VOLATILE IMPURITIES | Passes Test | Passes |
| BULK DENSITY | | 0.58 g/mL |
| TAP DENSITY | | 0.87 g/mL |
| PARTICAL SIZE (US 200) | % Retained | 83.7% |
| PARTICAL SIZE (US 325) | % Retained | 11.3 |

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Raw Material Comparison - Starch Pregelatinized NF (3088)

| | |
|--------------------|----------|
| P.O. # | 4027 |
| Test Type | Initial |
| Manufacturer | Colorcon |
| Manufacturer Lot # | 403107 |

| PARAMETERS | SPECIFICATIONS | RESULTS |
|------------------------|----------------|-----------|
| DESCRIPTION | Passes Test | Passes |
| IDENTIFICATION | Positive | Passes |
| PH | 4.5 - 7.0 | 5.9 |
| IRON | NMT 0.002% | <0.002 % |
| OXIDIZING SUBSTANCES | Passes Test | Passes |
| SULFUR DIOXIDE | NMT: 0.008% | Passes |
| MICROBIAL LIMITS | Passes Test | Passes |
| LOSS ON DRYING | NMT 14.0% | 8.8% |
| RESIDUE ON IGNITION | NMT 0.5% | 0.2% |
| BULK DENSITY | | 0.66 g/mL |
| TAP DENSITY | | 0.84 g/mL |
| PARTICAL SIZE (US 100) | % Accumulation | 2.7% |
| PARTICAL SIZE (US 200) | % Accumulation | 26.6% |
| PARTICAL SIZE (US 325) | % Accumulation | 51.5% |

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Rau Material Comparison - Microcrystalline Cellulose, NF (3059)

| | |
|--------------------|---------|
| P.O. # | 4023 |
| Test Type | Initial |
| Manufacturer | Mendell |
| Manufacturer Lot # | 4583 |

| PARAMETERS | SPECIFICATIONS | RESULTS |
|--------------------------|----------------|----------|
| DESCRIPTION | Passes Test | Passes |
| IDENTIFICATION | Positive | Passes |
| PH | 5.5 to 7.0 | 6.1 |
| LOSS ON DRYING | NMT 5.0% | 2.5% |
| RESIDUE ON IGNITION | NMT 0.05% | 0.02% |
| WATER SOLUBLE SUBSTANCES | NMT 0.16% | 0.10% |
| HEAVY METALS | NMT 0.001% | <0.001% |
| STARCH | Passes Test | Passes |
| ASSAY | 97.0% - 102.0% | 99.7% |
| BULK DENSITY | | 0.34 g/m |
| TAP DENSITY | | 0.43 g/m |
| PARTICAL SIZE (US 325) | % Retained | 44.7% |
| PARTICAL SIZE (US 200) | % Retained | 20.6% |
| PARTICAL SIZE (US 100) | % Retained | NIL |

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Raw Material Comparison - Lactose Anhydrous, NF (DT) (3050)

| | |
|--------------------|----------|
| P.O. # | 4015 |
| Test Type | Initial |
| Manufacturer | Quest |
| Manufacturer Lot # | MRP54536 |

| PARAMETERS | SPECIFICATIONS | RESULTS |
|--|---------------------------|----------|
| DESCRIPTION | Passes Test | Passes |
| IDENTIFICATION A | Positive | Passes |
| IDENTIFICATION B | Positive | Passes |
| CLARITY AND COLOR OF SOLUTION | Passes Test | Passes |
| LOSS ON DRYING | NMT 0.5% | 0.2% |
| SPECIFIC ROTATION | Between +54.8° and +55.5° | +55.2° |
| MICROBIAL LIMITS | NMT 100 per gm | Passes |
| WATER | NMT 1.0% | 0.4% |
| RESIDUE ON IGNITION | NMT 0.1% | 0.04% |
| HEAVY METALS | NMT 5 ppm | < 5 ppm |
| ACIDITY/ALKALINITY | Passes Test | Passes |
| PROTEIN AND LIGHT ABSORBING IMPURITIES | NMT 0.25 | Passes |
| ORGANIC VOLATILE IMPURITIES | Passes Test | Passes |
| BULK DENSITY | | 0.57 g/m |
| TAP DENSITY | | 0.81 g/m |
| PARTICAL SIZE (US 100) | % Accumulation | 13.1% |
| PARTICAL SIZE (US 200) | % Accumulation | 28.6% |
| PARTICAL SIZE (US 325) | % Accumulation | 40.5% |

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Rau Material Comparison - Stearic Acid, NF (3089)

| | |
|--------------------|---------|
| P.O.# | 3910 |
| Test Type | Initial |
| Manufacturer | Witco |
| Manufacturer Lot # | 440069 |

| PARAMETERS | SPECIFICATIONS | RESULTS |
|-----------------------------|----------------|-----------|
| DESCRIPTION | Passes Test | Passes |
| CONGEALING TEMPERATURE | NLT 54° | 55° |
| RESIDUE ON IGNITION | NMT 0.1% | 0.01 |
| HEAVY METALS | NMT 0.001% | <0.001 |
| MINERAL ACID | Passes Test | Passes |
| NEUTRAL FAT OR PARAFIN | Passes Test | Passes |
| IODINE VALUE | NMT 4 | 0.10 |
| ASSAY A | NLT 40.0% | 43.4% |
| ASSAY B | NLT 90.0% | 96.4% |
| ORGANIC VOLATILE IMPURITIES | Passes Test | Passes |
| BULK DENSITY | | 0.38 g/ml |
| TAP DENSITY | | 0.49 g/ml |
| PARTICAL SIZE (US 325) | % Retained | 54.0% |
| PARTICAL SIZE (US 200) | % Retained | 6.4% |

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Raw Material Comparison - Silicon Dioxide, NF (3081)

| | |
|--------------------|----------------|
| P.O. # | 3696 |
| Test Type | Initial |
| Manufacturer | Dequessa Corp. |
| Manufacturer Lot # | 4-90 |

| PARAMETERS | SPECIFICATIONS | RESULTS |
|------------------------|----------------|-----------|
| DESCRIPTION | Passes Test | Passes |
| IDENTIFICATION | Positive | Passes |
| PH | 4 - 8 | 6.7 |
| LOSS ON DRYING | NMT 5.0% | 4.0% |
| CHLORIDE | NMT 0.1% | <0.1% |
| SULFATE | NMT 0.5% | <0.5% |
| ARSENIC | NMT 3 ppm | <3 ppm |
| HEAVY METAL | NMT 0.003% | <0.003% |
| ASSAY | NLT 99.0% | 99.6% |
| BULK DENSITY | | 0.10 g/ml |
| TAP DENSITY | | 0.13 g/ml |
| PARTICAL SIZE (US 325) | % Retained | Nil |

**AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION**

DIGOXIN TABLETS, 0.125 mg MPR NO. 14502 - 00

PROTOCOL STEP - TEMPERATURE/HUMIDITY READINGS

Temperature and humidity readings will be taken in the production area. These three batches ran in production between 11/8/94 and 11/18/94.

RESULTS - See attached data summary sheets.

CONCLUSIONS AND COMMENTS

The temperature ranged from 58 - 65° F, and the relative humidity from 43 - 58%. It should be noted that this is the first production in the new production rooms and that inadvertently some readings were not taken. The data collected indicates that acceptable product can be made under these conditions.

AMIDE PHARMACEUTICAL, INC.

TEMPERATURE/HUMIDITY READINGS

PERIOD COVERING DIGOXIN TABLETS, 0.125 mg

BATCHES 4318A, 4320A, AND 4322A

| LOCATION | DATE | TEMP. (Deg. F) | RH (%) |
|-------------------|-----------|----------------|--------|
| Near Pr. Rm. #117 | 11-Nov-94 | 58 | 43 |
| Near Pr. Rm. #117 | 18-Nov-94 | 65 | 58 |

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg MPR NO. 14502 - 00

STEP - BLEND UNIFORMITY

Utilizing a sampling thief, sample each of the blenders from the positions shown on the attached data summary. Separately analyze, and report, each one for active ingredient content.

The speed of each blender will be monitored both empty and at each stage of blending.

ACCEPTANCE CRITERIA

Final Blend - 85.0 - 115.0 % Th. (Individual)

RESULTS - See the attached data summary.

CONCLUSIONS AND COMMENTS

The final blends for the three batches met all acceptance criteria and appear to be uniformly blended.

The bulk and tamped density results are comparable for all three batches.

The speed for both blenders was observed to be constant throughout production of the three batches. The same speed was obtained both empty and under load. The supporting documentation is attached.

3 Cu. Ft. (32) - 22 rpm
10 Cu. Ft. (35) - 16 rpm

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

FINAL BLEND - Assay (% Label)

| | Batch # | Batch # | Batch # |
|---------------------------|---------|---------|---------|
| | 4318A | 4320A | 4322A |
| Left Column - Top Left | 98.1 | 96.4 | 97.6 |
| Left Column - Top Center | 97.9 | 97.8 | 98.1 |
| Left Column - Top Right | 98.6 | 97.2 | 98.6 |
| Right Column - Top Left | 97.9 | 99.6 | 98.0 |
| Right Column - Top Center | 98.3 | 98.0 | 97.5 |
| Right Column - Top Right | 98.3 | 98.4 | 98.3 |
| Middle Left | 96.8 | 99.2 | 99.4 |
| Middle Center | 100.1 | 100.4 | 100.1 |
| Middle Right | 100.1 | 100.8 | 98.1 |
| Bottom Left | 98.0 | 98.0 | 96.7 |
| Bottom Right | 99.0 | 100.7 | 99.1 |
| Average | 98.5 | 98.8 | 98.3 |
| St Dev. | 1.0 | 1.5 | 1.0 |
| RSD | 1.0 | 1.5 | 1.0 |

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

FINAL BLEND - Density/Particle Size - Batch # 4318A

Density (g/ml)

| | Top Center | Top Left | Top Right |
|------|------------|----------|-----------|
| Bulk | 0.61 | 0.61 | 0.61 |
| Tap | 0.89 | 0.89 | 0.90 |

Particle Size (% Retained)

| Mesh Size | Top Center | Top Left | Top Right |
|-----------|------------|----------|-----------|
| 325 | 54.5 | 53.3 | 54.3 |
| 200 | 34.8 | 34.5 | 34.8 |
| 100 | 14.6 | 14.9 | 15.1 |
| 60 | 4.4 | 4.5 | 4.2 |
| 40 | Nil | Nil | Nil |

FINAL BLEND - Density/Particle Size - Batch # 4320A

Density (g/ml)

| | Top Center | Top Left | Top Right |
|------|------------|----------|-----------|
| Bulk | 0.62 | 0.61 | 0.61 |
| Tap | 0.91 | 0.90 | 0.90 |

Particle Size (% Retained)

| Mesh Size | Top Center | Top Left | Top Right |
|-----------|------------|----------|-----------|
| 325 | 53.7 | 53.7 | 53.6 |
| 200 | 34.3 | 34.5 | 34.1 |
| 100 | 14.9 | 15.2 | 15.1 |
| 60 | 4.2 | 4.5 | 4.7 |
| 40 | Nil | Nil | Nil |

FINAL BLEND - Density/Particle Size - Batch # 4322A

Density (g/ml)

| | Top Center | Top Left | Top Right |
|------|------------|----------|-----------|
| Bulk | 0.61 | 0.61 | 0.61 |
| Tap | 0.90 | 0.90 | 0.90 |

Particle Size (% Retained)

| Mesh Size | Top Center | Top Left | Top Right |
|-----------|------------|----------|-----------|
| 325 | 53.1 | 53.4 | 53.0 |
| 200 | 34.1 | 34.6 | 34.2 |
| 100 | 15.3 | 15.3 | 15.1 |
| 60 | 4.2 | 4.1 | 4.4 |
| 40 | Nil | Nil | Nil |

BLENDER #: 35

FD-2-046

PROCESS VALIDATION DATA SHEET

BATCH #: 4320A

MPR #: 14502

REV # 00

DATE: 11/10/94

BLENDER #: 35

[illegible]

PD2-046

PRODUCT NAME (1): Digoxin Tablets 0.125mg (145)

BATCH #: 4322A

MPR #: 14502

REV 11 00

DATE: 11/11/94

BLENDER #: 32

PD2-046

BLENDER #: 35

PD2-046

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg MPR NO. 14502 - 00

PROTOCOL STEP - COMPRESSION

Samples were taken from each side of the press each 30 minutes and were evaluated for the following parameters.

Weight (n = 10)
Thickness (n = 5)
Hardness (n = 5)

These samples will be arranged chronologically and the batch divided into thirds. Front and rear will be analyzed separately as follows.

| | |
|----------------|---------------------------|
| Friability | 10 g - 1 run |
| Dissolution | N = 12 (6 front & 6 rear) |
| Disintegration | N = 6 |

Content uniformity is to be run across the entire batch. One tablet from each sample taken is to be run from the front, and one from the rear. A minimum of 30 is required from each side.

During compression a minimum quantity of tablets will be run at speeds higher and lower than normal. The actual speeds will be selected during production. These tablets will be evaluated for weight and hardness.

During compression minimum quantities of tablets will be run at hardness of 0.5 - 2 KP and greater than 6 KP. An attempt will also be made to run some tablets at the highest possible hardness that can be obtained without capping. These tablets will be evaluated for Dissolution and Friability.

ACCEPTANCE CRITERIA

Weight: 0.097 - 0.113 g
Hardness: 1.0 - 6.0 KP
Thickness: 2.0 - 3.0 mm
Friability: NMT 1.0 %
Dissolution: Meets USP Requirement
Disintegration: N/A (for characterization only)
Content Uniformity: 85.0 - 115.0 % TH, (RSD NMT 6.0 %)
Assay: 90.0 - 105.0 % Label

RESULTS - See attached data summary sheets.

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg MPR NO. 14502 - 00

CONCLUSIONS AND COMMENTS

The samples met all acceptance criteria.

The values for weight, hardness, and thickness for the three batches were comparable to each other and showed no unusual shifts or trends. The overall averages for weight, hardness and thickness are very close to the midpoints of the preset ranges. Therefore, no revisions to these limits are indicated by the validation data. Results are attached in both tabular and graphical form.

Content Uniformity was within limits for all samples tested, with no significant trends being observed. All values were within 93 - 105 % Label. The values obtained were observed to agree favorably with the blend assays. It should be noted that the averages for the blend assays, and the content uniformity results are essentially the label amount.

All Dissolution samples for the three batches met the USP requirements. This statement is true for both USP XXII (60 Min.) and XXIII (15 & 60 Min.). The values for the three batches were comparable.

Friability values were all well within the acceptance criteria, and comparable for the three batches.

Disintegration results were comparable with no unusual shifts or trends. Note that this test was run for characterization only, and therefore no acceptance criteria have been, or will be, established.

Acceptable tablets were produced at the low press speed for all three batches, and at high speed for batches 4318A & 4320A. Unacceptable tablets (weight variability) were produced at high speed for batch 4322A. The normal, high, and low operating speeds for each batch are as follows. Based on the data obtained here, the press may be safely run as slow as 14 rpm. No upper limit can be set at this time.

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg MPR NO. 14502 - 00

| BATCH | NORMAL | HIGH | LOW |
|-------|--------|--------|--------|
| 4318A | 21 rpm | 26 rpm | 14 rpm |
| 4320A | 21 rpm | 26 rpm | 14 rpm |
| 4322A | 21 rpm | 26 rpm | 14 rpm |

The high and low hardness validation produced acceptable tablets at both ends of the range. Tablets with hardness above the upper limit could not be produced. Therefore the guideline will remain at 1.0 - 6.0 KP. The values for friability are listed below. Those for dissolution are attached.

| | | FRIABILITY (%) | | |
|---------|-------|----------------|-------|-------|
| | BATCH | 4318A | 4320A | 4322A |
| LOW KP | FRONT | 0.2 | 0.2 | 0.04 |
| | REAR | 0.1 | 0.2 | 0.2 |
| HIGH KP | FRONT | 0.03 | 0.1 | 0.04 |
| | REAR | 0.04 | 0.04 | 0.1 |

The results for the overall composites are attached. These are also all within the acceptance criteria, and are essentially comparable to those obtained for the individual samples.

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg - Batch # 4318A**

Compression - Height (g) - Front

| Date | Time | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Average | St Dev. | RSD |
|----------|----------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|---------|---------|-----|
| 11/11/94 | 1:50 PM | 0.105 | 0.104 | 0.105 | 0.106 | 0.106 | 0.106 | 0.107 | 0.105 | 0.102 | 0.104 | 0.105 | 0.001 | 1.3 |
| 11/11/94 | 2:45 PM | 0.104 | 0.105 | 0.105 | 0.105 | 0.104 | 0.107 | 0.104 | 0.103 | 0.105 | 0.103 | 0.105 | 0.001 | 1.1 |
| 11/11/94 | 3:20 PM | 0.106 | 0.106 | 0.108 | 0.105 | 0.107 | 0.106 | 0.106 | 0.105 | 0.108 | 0.107 | 0.106 | 0.001 | 1.0 |
| 11/11/94 | 4:00 PM | 0.105 | 0.106 | 0.108 | 0.105 | 0.103 | 0.106 | 0.104 | 0.106 | 0.104 | 0.106 | 0.105 | 0.001 | 1.3 |
| 11/11/94 | 4:30 PM | 0.108 | 0.104 | 0.105 | 0.107 | 0.108 | 0.107 | 0.105 | 0.106 | 0.105 | 0.106 | 0.106 | 0.001 | 1.3 |
| 11/12/94 | 7:25 AM | 0.108 | 0.107 | 0.107 | 0.106 | 0.107 | 0.107 | 0.108 | 0.106 | 0.106 | 0.107 | 0.107 | 0.001 | 0.7 |
| 11/12/94 | 7:55 AM | 0.106 | 0.109 | 0.108 | 0.106 | 0.108 | 0.106 | 0.110 | 0.107 | 0.108 | 0.108 | 0.108 | 0.001 | 1.3 |
| 11/12/94 | 8:25 AM | 0.105 | 0.107 | 0.104 | 0.106 | 0.105 | 0.112 | 0.106 | 0.107 | 0.105 | 0.105 | 0.106 | 0.002 | 2.1 |
| 11/12/94 | 8:55 AM | 0.109 | 0.107 | 0.104 | 0.105 | 0.105 | 0.105 | 0.103 | 0.107 | 0.107 | 0.105 | 0.106 | 0.002 | 1.7 |
| 11/12/94 | 9:25 AM | 0.105 | 0.106 | 0.106 | 0.104 | 0.106 | 0.106 | 0.107 | 0.105 | 0.107 | 0.106 | 0.106 | 0.001 | 0.9 |
| 11/12/94 | 9:55 AM | 0.106 | 0.109 | 0.106 | 0.108 | 0.104 | 0.107 | 0.106 | 0.106 | 0.104 | 0.107 | 0.106 | 0.002 | 1.5 |
| 11/12/94 | 10:25 AM | 0.103 | 0.104 | 0.108 | 0.107 | 0.107 | 0.105 | 0.108 | 0.105 | 0.108 | 0.106 | 0.106 | 0.002 | 1.7 |
| 11/12/94 | 11:50 AM | 0.105 | 0.108 | 0.106 | 0.103 | 0.106 | 0.107 | 0.105 | 0.103 | 0.104 | 0.106 | 0.105 | 0.002 | 1.6 |
| 11/12/94 | 12:20 PM | 0.098 | 0.106 | 0.105 | 0.104 | 0.105 | 0.105 | 0.108 | 0.105 | 0.104 | 0.107 | 0.105 | 0.003 | 2.5 |
| 11/12/94 | 12:50 PM | 0.105 | 0.106 | 0.105 | 0.107 | 0.104 | 0.106 | 0.106 | 0.109 | 0.107 | 0.105 | 0.106 | 0.001 | 1.3 |
| 11/12/94 | 1:20 PM | 0.106 | 0.104 | 0.105 | 0.104 | 0.106 | 0.103 | 0.105 | 0.104 | 0.104 | 0.105 | 0.105 | 0.001 | 0.9 |
| 11/12/94 | 1:50 PM | 0.103 | 0.104 | 0.103 | 0.106 | 0.104 | 0.104 | 0.104 | 0.107 | 0.105 | 0.105 | 0.105 | 0.001 | 1.2 |
| 11/12/94 | 2:20 PM | 0.105 | 0.103 | 0.104 | 0.105 | 0.105 | 0.105 | 0.105 | 0.104 | 0.105 | 0.106 | 0.105 | 0.001 | 0.8 |
| 11/14/94 | 8:20 AM | 0.106 | 0.104 | 0.106 | 0.104 | 0.105 | 0.105 | 0.104 | 0.109 | 0.105 | 0.103 | 0.105 | 0.002 | 1.6 |
| 11/14/94 | 8:45 AM | 0.104 | 0.105 | 0.103 | 0.106 | 0.106 | 0.106 | 0.106 | 0.107 | 0.103 | 0.104 | 0.105 | 0.001 | 1.3 |
| 11/14/94 | 9:15 AM | 0.106 | 0.106 | 0.107 | 0.107 | 0.105 | 0.105 | 0.105 | 0.106 | 0.106 | 0.106 | 0.106 | 0.001 | 0.7 |
| 11/14/94 | 9:45 AM | 0.105 | 0.106 | 0.106 | 0.104 | 0.106 | 0.105 | 0.104 | 0.104 | 0.105 | 0.106 | 0.105 | 0.001 | 0.8 |
| 11/14/94 | 10:15 AM | 0.104 | 0.105 | 0.106 | 0.104 | 0.106 | 0.104 | 0.105 | 0.103 | 0.105 | 0.106 | 0.105 | 0.001 | 1.0 |
| 11/14/94 | 10:45 AM | 0.106 | 0.106 | 0.106 | 0.103 | 0.105 | 0.107 | 0.106 | 0.107 | 0.106 | 0.107 | 0.105 | 0.001 | 1.4 |
| 11/14/94 | 1:25 PM | 0.103 | 0.105 | 0.104 | 0.105 | 0.102 | 0.107 | 0.107 | 0.106 | 0.104 | 0.104 | 0.105 | 0.002 | 1.6 |
| 11/14/94 | 1:50 PM | 0.106 | 0.103 | 0.105 | 0.105 | 0.103 | 0.104 | 0.107 | 0.104 | 0.106 | 0.104 | 0.105 | 0.001 | 1.3 |
| 11/14/94 | 2:45 PM | 0.105 | 0.105 | 0.106 | 0.106 | 0.105 | 0.106 | 0.104 | 0.105 | 0.106 | 0.102 | 0.105 | 0.001 | 1.2 |

Compression - Weight (g) - Rear

| Date | Time | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Average | St Dev. | RSD |
|----------|----------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|---------|---------|-----|
| 11/11/94 | 1:50 PM | 0.106 | 0.102 | 0.104 | 0.104 | 0.100 | 0.107 | 0.103 | 0.104 | 0.106 | 0.103 | 0.104 | 0.002 | 2.0 |
| 11/11/94 | 2:45 PM | 0.105 | 0.107 | 0.104 | 0.105 | 0.106 | 0.102 | 0.105 | 0.107 | 0.105 | 0.104 | 0.105 | 0.001 | 1.4 |
| 11/11/94 | 3:20 PM | 0.107 | 0.102 | 0.104 | 0.108 | 0.106 | 0.105 | 0.103 | 0.105 | 0.108 | 0.103 | 0.105 | 0.002 | 2.0 |
| 11/11/94 | 4:00 PM | 0.103 | 0.108 | 0.109 | 0.105 | 0.106 | 0.103 | 0.104 | 0.103 | 0.107 | 0.107 | 0.106 | 0.002 | 2.1 |
| 11/11/94 | 4:30 PM | 0.106 | 0.101 | 0.106 | 0.108 | 0.104 | 0.107 | 0.106 | 0.103 | 0.105 | 0.100 | 0.105 | 0.003 | 2.5 |
| 11/12/94 | 7:25 AM | 0.102 | 0.105 | 0.106 | 0.109 | 0.107 | 0.107 | 0.104 | 0.105 | 0.108 | 0.107 | 0.106 | 0.002 | 1.9 |
| 11/12/94 | 7:55 AM | 0.109 | 0.104 | 0.105 | 0.108 | 0.107 | 0.109 | 0.108 | 0.107 | 0.103 | 0.101 | 0.106 | 0.003 | 2.6 |
| 11/12/94 | 8:25 AM | 0.106 | 0.108 | 0.103 | 0.104 | 0.107 | 0.107 | 0.109 | 0.103 | 0.107 | 0.109 | 0.106 | 0.002 | 2.1 |
| 11/12/94 | 8:55 AM | 0.103 | 0.104 | 0.107 | 0.108 | 0.109 | 0.107 | 0.107 | 0.109 | 0.103 | 0.105 | 0.106 | 0.002 | 2.2 |
| 11/12/94 | 9:25 AM | 0.106 | 0.103 | 0.102 | 0.104 | 0.104 | 0.102 | 0.104 | 0.106 | 0.100 | 0.105 | 0.104 | 0.002 | 1.8 |
| 11/12/94 | 9:55 AM | 0.106 | 0.103 | 0.107 | 0.107 | 0.108 | 0.104 | 0.104 | 0.106 | 0.100 | 0.105 | 0.104 | 0.002 | 1.9 |
| 11/12/94 | 10:25 AM | 0.104 | 0.105 | 0.102 | 0.104 | 0.106 | 0.105 | 0.107 | 0.104 | 0.106 | 0.104 | 0.105 | 0.001 | 1.4 |
| 11/12/94 | 11:50 AM | 0.107 | 0.107 | 0.107 | 0.107 | 0.100 | 0.108 | 0.105 | 0.102 | 0.107 | 0.106 | 0.106 | 0.003 | 2.5 |
| 11/12/94 | 12:20 PM | 0.107 | 0.105 | 0.108 | 0.104 | 0.107 | 0.103 | 0.102 | 0.104 | 0.107 | 0.107 | 0.105 | 0.002 | 2.0 |
| 11/12/94 | 12:50 PM | 0.106 | 0.105 | 0.107 | 0.104 | 0.108 | 0.106 | 0.110 | 0.106 | 0.105 | 0.105 | 0.106 | 0.002 | 1.6 |
| 11/12/94 | 1:20 PM | 0.106 | 0.105 | 0.106 | 0.105 | 0.104 | 0.104 | 0.107 | 0.106 | 0.107 | 0.110 | 0.106 | 0.002 | 1.7 |
| 11/12/94 | 1:50 PM | 0.107 | 0.107 | 0.107 | 0.106 | 0.107 | 0.105 | 0.105 | 0.108 | 0.107 | 0.105 | 0.106 | 0.001 | 1.0 |
| 11/12/94 | 2:20 PM | 0.106 | 0.107 | 0.105 | 0.107 | 0.104 | 0.107 | 0.106 | 0.109 | 0.106 | 0.107 | 0.106 | 0.001 | 1.3 |
| 11/14/94 | 8:20 AM | 0.104 | 0.105 | 0.103 | 0.108 | 0.105 | 0.106 | 0.104 | 0.108 | 0.107 | 0.104 | 0.105 | 0.002 | 1.7 |
| 11/14/94 | 8:45 AM | 0.101 | 0.107 | 0.104 | 0.104 | 0.106 | 0.103 | 0.104 | 0.105 | 0.107 | 0.105 | 0.105 | 0.002 | 1.8 |
| 11/14/94 | 9:15 AM | 0.106 | 0.104 | 0.106 | 0.104 | 0.102 | 0.104 | 0.105 | 0.107 | 0.105 | 0.104 | 0.105 | 0.001 | 1.4 |
| 11/14/94 | 9:45 AM | 0.107 | 0.106 | 0.104 | 0.104 | 0.103 | 0.102 | 0.106 | 0.103 | 0.106 | 0.106 | 0.105 | 0.002 | 1.6 |
| 11/14/94 | 10:15 AM | 0.103 | 0.105 | 0.103 | 0.107 | 0.105 | 0.106 | 0.104 | 0.104 | 0.105 | 0.106 | 0.105 | 0.001 | 1.3 |
| 11/14/94 | 10:45 AM | 0.105 | 0.101 | 0.105 | 0.108 | 0.103 | 0.102 | 0.102 | 0.106 | 0.104 | 0.106 | 0.104 | 0.002 | 2.1 |
| 11/14/94 | 1:25 PM | 0.107 | 0.103 | 0.103 | 0.106 | 0.105 | 0.106 | 0.103 | 0.106 | 0.105 | 0.109 | 0.105 | 0.002 | 1.8 |
| 11/14/94 | 1:50 PM | 0.103 | 0.104 | 0.102 | 0.104 | 0.110 | 0.105 | 0.107 | 0.105 | 0.106 | 0.104 | 0.105 | 0.002 | 2.2 |
| 11/14/94 | 2:45 PM | 0.104 | 0.104 | 0.103 | 0.106 | 0.106 | 0.106 | 0.107 | 0.103 | 0.103 | 0.107 | 0.105 | 0.002 | 1.6 |

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg - Batch # 4320A**

Compression - Weight (g) - Front

| Date | Time | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Average | St Dev. | RSD |
|----------|----------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|---------|---------|-----|
| 11/14/94 | 5:15 PM | 0.104 | 0.105 | 0.106 | 0.105 | 0.105 | 0.104 | 0.103 | 0.107 | 0.104 | 0.105 | 0.105 | 0.001 | 1.1 |
| 11/14/94 | 5:45 PM | 0.106 | 0.106 | 0.104 | 0.103 | 0.105 | 0.105 | 0.105 | 0.102 | 0.103 | 0.104 | 0.104 | 0.001 | 1.3 |
| 11/14/94 | 6:15 PM | 0.107 | 0.105 | 0.104 | 0.104 | 0.104 | 0.104 | 0.108 | 0.106 | 0.106 | 0.104 | 0.105 | 0.001 | 1.4 |
| 11/14/94 | 6:45 PM | 0.102 | 0.106 | 0.103 | 0.106 | 0.104 | 0.106 | 0.107 | 0.103 | 0.105 | 0.105 | 0.105 | 0.002 | 1.6 |
| 11/14/94 | 7:15 PM | 0.106 | 0.105 | 0.104 | 0.104 | 0.102 | 0.106 | 0.103 | 0.103 | 0.105 | 0.103 | 0.104 | 0.001 | 1.3 |
| 11/14/94 | 7:45 PM | 0.107 | 0.104 | 0.105 | 0.104 | 0.104 | 0.106 | 0.106 | 0.105 | 0.103 | 0.106 | 0.105 | 0.001 | 1.2 |
| 11/14/94 | 8:15 PM | 0.106 | 0.105 | 0.105 | 0.107 | 0.107 | 0.105 | 0.105 | 0.107 | 0.108 | 0.109 | 0.106 | 0.001 | 1.3 |
| 11/14/94 | 8:45 PM | 0.104 | 0.106 | 0.108 | 0.107 | 0.109 | 0.106 | 0.106 | 0.105 | 0.107 | 0.105 | 0.106 | 0.001 | 1.4 |
| 11/15/94 | 8:00 AM | 0.108 | 0.105 | 0.109 | 0.104 | 0.106 | 0.107 | 0.108 | 0.107 | 0.107 | 0.106 | 0.107 | 0.001 | 1.4 |
| 11/15/94 | 8:30 AM | 0.105 | 0.106 | 0.106 | 0.104 | 0.104 | 0.107 | 0.107 | 0.104 | 0.106 | 0.104 | 0.105 | 0.001 | 1.2 |
| 11/15/94 | 9:00 AM | 0.107 | 0.104 | 0.106 | 0.103 | 0.105 | 0.106 | 0.104 | 0.105 | 0.104 | 0.107 | 0.105 | 0.001 | 1.3 |
| 11/15/94 | 9:30 AM | 0.107 | 0.107 | 0.106 | 0.106 | 0.106 | 0.106 | 0.107 | 0.105 | 0.105 | 0.107 | 0.106 | 0.001 | 0.7 |
| 11/15/94 | 10:00 AM | 0.104 | 0.104 | 0.101 | 0.106 | 0.106 | 0.103 | 0.103 | 0.103 | 0.104 | 0.103 | 0.104 | 0.001 | 1.4 |
| 11/15/94 | 10:30 AM | 0.104 | 0.105 | 0.106 | 0.105 | 0.104 | 0.106 | 0.104 | 0.106 | 0.105 | 0.105 | 0.105 | 0.001 | 0.8 |
| 11/15/94 | 11:35 AM | 0.107 | 0.106 | 0.104 | 0.107 | 0.106 | 0.105 | 0.106 | 0.105 | 0.107 | 0.106 | 0.106 | 0.001 | 0.9 |
| 11/15/94 | 12:05 PM | 0.104 | 0.105 | 0.108 | 0.103 | 0.107 | 0.106 | 0.105 | 0.106 | 0.105 | 0.106 | 0.106 | 0.001 | 1.4 |
| 11/15/94 | 12:35 PM | 0.107 | 0.106 | 0.105 | 0.107 | 0.107 | 0.105 | 0.106 | 0.104 | 0.104 | 0.105 | 0.106 | 0.001 | 1.1 |
| 11/15/94 | 1:05 PM | 0.106 | 0.104 | 0.107 | 0.105 | 0.107 | 0.106 | 0.105 | 0.104 | 0.105 | 0.106 | 0.106 | 0.001 | 1.0 |
| 11/15/94 | 1:35 PM | 0.105 | 0.106 | 0.104 | 0.106 | 0.104 | 0.108 | 0.107 | 0.106 | 0.105 | 0.105 | 0.106 | 0.001 | 1.2 |
| 11/15/94 | 4:30 PM | 0.105 | 0.108 | 0.107 | 0.108 | 0.106 | 0.104 | 0.105 | 0.107 | 0.107 | 0.104 | 0.106 | 0.002 | 1.4 |
| 11/15/94 | 5:00 PM | 0.105 | 0.105 | 0.106 | 0.107 | 0.108 | 0.105 | 0.105 | 0.107 | 0.105 | 0.105 | 0.106 | 0.001 | 1.1 |
| 11/15/94 | 5:30 PM | 0.107 | 0.105 | 0.104 | 0.106 | 0.104 | 0.105 | 0.107 | 0.104 | 0.106 | 0.106 | 0.105 | 0.001 | 1.1 |
| 11/15/94 | 6:10 PM | 0.106 | 0.104 | 0.105 | 0.105 | 0.107 | 0.102 | 0.107 | 0.106 | 0.104 | 0.108 | 0.105 | 0.002 | 1.7 |
| 11/15/94 | 6:40 PM | 0.103 | 0.104 | 0.106 | 0.104 | 0.106 | 0.105 | 0.102 | 0.106 | 0.106 | 0.105 | 0.105 | 0.001 | 1.4 |
| 11/15/94 | 7:10 PM | 0.103 | 0.105 | 0.103 | 0.106 | 0.103 | 0.106 | 0.105 | 0.105 | 0.102 | 0.106 | 0.104 | 0.002 | 1.4 |
| 11/15/94 | 7:40 PM | 0.104 | 0.105 | 0.105 | 0.105 | 0.104 | 0.103 | 0.107 | 0.105 | 0.105 | 0.107 | 0.105 | 0.001 | 1.2 |
| 11/15/94 | 8:10 PM | 0.104 | 0.105 | 0.104 | 0.104 | 0.106 | 0.105 | 0.104 | 0.106 | 0.104 | 0.104 | 0.105 | 0.001 | 0.8 |
| 11/15/94 | 8:40 AM | 0.106 | 0.104 | 0.105 | 0.103 | 0.102 | 0.105 | 0.104 | 0.105 | 0.103 | 0.103 | 0.104 | 0.001 | 1.2 |
| 11/15/94 | 9:10 AM | 0.103 | 0.106 | 0.106 | 0.104 | 0.104 | 0.105 | 0.105 | 0.103 | 0.104 | 0.107 | 0.105 | 0.001 | 1.3 |

Compression - Weight (g) - Rear

| Date | Time | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Average | St Dev. | RSD |
|----------|----------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|---------|---------|-----|
| 11/14/94 | 5:15 PM | 0.107 | 0.103 | 0.102 | 0.107 | 0.103 | 0.108 | 0.105 | 0.104 | 0.105 | 0.101 | 0.105 | 0.002 | 2.2 |
| 11/14/94 | 5:45 PM | 0.104 | 0.105 | 0.102 | 0.105 | 0.105 | 0.105 | 0.101 | 0.103 | 0.106 | 0.105 | 0.104 | 0.002 | 1.5 |
| 11/14/94 | 6:15 PM | 0.106 | 0.102 | 0.100 | 0.105 | 0.101 | 0.105 | 0.104 | 0.106 | 0.106 | 0.104 | 0.104 | 0.002 | 2.1 |
| 11/14/94 | 6:45 PM | 0.104 | 0.100 | 0.101 | 0.100 | 0.100 | 0.102 | 0.104 | 0.102 | 0.102 | 0.100 | 0.102 | 0.002 | 1.6 |
| 11/14/94 | 7:15 PM | 0.104 | 0.101 | 0.100 | 0.102 | 0.101 | 0.104 | 0.104 | 0.100 | 0.100 | 0.101 | 0.102 | 0.002 | 1.7 |
| 11/14/94 | 7:45 PM | 0.108 | 0.102 | 0.107 | 0.106 | 0.107 | 0.103 | 0.104 | 0.104 | 0.104 | 0.105 | 0.105 | 0.002 | 1.9 |
| 11/14/94 | 8:15 PM | 0.108 | 0.104 | 0.107 | 0.108 | 0.105 | 0.104 | 0.106 | 0.104 | 0.108 | 0.108 | 0.106 | 0.002 | 1.7 |
| 11/14/94 | 8:45 PM | 0.108 | 0.106 | 0.107 | 0.104 | 0.108 | 0.106 | 0.106 | 0.105 | 0.102 | 0.106 | 0.106 | 0.002 | 1.7 |
| 11/15/94 | 8:00 AM | 0.107 | 0.105 | 0.107 | 0.104 | 0.107 | 0.108 | 0.110 | 0.108 | 0.108 | 0.107 | 0.107 | 0.002 | 1.6 |
| 11/15/94 | 8:30 AM | 0.102 | 0.105 | 0.102 | 0.104 | 0.105 | 0.104 | 0.106 | 0.105 | 0.103 | 0.102 | 0.104 | 0.001 | 1.4 |
| 11/15/94 | 9:00 AM | 0.106 | 0.104 | 0.101 | 0.106 | 0.101 | 0.102 | 0.107 | 0.107 | 0.103 | 0.103 | 0.104 | 0.002 | 2.3 |
| 11/15/94 | 9:30 AM | 0.107 | 0.105 | 0.101 | 0.107 | 0.104 | 0.102 | 0.106 | 0.103 | 0.106 | 0.104 | 0.105 | 0.002 | 2.0 |
| 11/15/94 | 10:00 AM | 0.105 | 0.103 | 0.105 | 0.104 | 0.104 | 0.105 | 0.107 | 0.103 | 0.105 | 0.105 | 0.105 | 0.001 | 1.1 |
| 11/15/94 | 10:30 AM | 0.103 | 0.102 | 0.106 | 0.105 | 0.103 | 0.103 | 0.106 | 0.104 | 0.106 | 0.109 | 0.105 | 0.002 | 2.0 |
| 11/15/94 | 11:35 AM | 0.107 | 0.108 | 0.105 | 0.103 | 0.103 | 0.104 | 0.103 | 0.102 | 0.103 | 0.104 | 0.104 | 0.002 | 1.9 |
| 11/15/94 | 12:05 PM | 0.108 | 0.105 | 0.104 | 0.107 | 0.103 | 0.107 | 0.107 | 0.106 | 0.106 | 0.104 | 0.106 | 0.002 | 1.5 |
| 11/15/94 | 12:35 PM | 0.107 | 0.104 | 0.106 | 0.103 | 0.107 | 0.102 | 0.106 | 0.106 | 0.105 | 0.106 | 0.105 | 0.002 | 1.6 |
| 11/15/94 | 1:05 PM | 0.102 | 0.105 | 0.103 | 0.107 | 0.101 | 0.107 | 0.105 | 0.103 | 0.107 | 0.105 | 0.105 | 0.002 | 2.1 |
| 11/15/94 | 1:35 PM | 0.105 | 0.106 | 0.106 | 0.105 | 0.105 | 0.106 | 0.103 | 0.102 | 0.102 | 0.106 | 0.105 | 0.002 | 1.6 |
| 11/15/94 | 4:30 PM | 0.106 | 0.104 | 0.106 | 0.105 | 0.107 | 0.102 | 0.107 | 0.103 | 0.104 | 0.105 | 0.105 | 0.002 | 1.7 |
| 11/15/94 | 5:00 PM | 0.109 | 0.105 | 0.107 | 0.107 | 0.106 | 0.106 | 0.106 | 0.105 | 0.107 | 0.103 | 0.106 | 0.002 | 1.5 |
| 11/15/94 | 5:30 PM | 0.106 | 0.104 | 0.104 | 0.106 | 0.104 | 0.105 | 0.107 | 0.106 | 0.106 | 0.103 | 0.105 | 0.001 | 1.2 |
| 11/15/94 | 6:10 PM | 0.104 | 0.104 | 0.107 | 0.104 | 0.104 | 0.103 | 0.103 | 0.103 | 0.106 | 0.102 | 0.104 | 0.001 | 1.4 |
| 11/15/94 | 6:40 PM | 0.104 | 0.105 | 0.103 | 0.104 | 0.102 | 0.105 | 0.101 | 0.103 | 0.105 | 0.106 | 0.104 | 0.002 | 1.5 |
| 11/15/94 | 7:10 PM | 0.104 | 0.103 | 0.107 | 0.100 | 0.104 | 0.102 | 0.105 | 0.104 | 0.105 | 0.104 | 0.104 | 0.002 | 1.8 |
| 11/15/94 | 7:40 PM | 0.106 | 0.105 | 0.105 | 0.106 | 0.106 | 0.106 | 0.106 | 0.104 | 0.106 | 0.106 | 0.105 | 0.001 | 0.8 |
| 11/15/94 | 8:10 PM | 0.103 | 0.103 | 0.103 | 0.105 | 0.105 | 0.103 | 0.103 | 0.102 | 0.106 | 0.102 | 0.104 | 0.001 | 1.4 |
| 11/15/94 | 8:40 AM | 0.105 | 0.102 | 0.106 | 0.106 | 0.106 | 0.104 | 0.101 | 0.102 | 0.103 | 0.104 | 0.104 | 0.002 | 1.8 |
| 11/15/94 | 9:10 AM | 0.101 | 0.105 | 0.101 | 0.106 | 0.106 | 0.105 | 0.102 | 0.105 | 0.102 | 0.103 | 0.104 | 0.002 | 1.9 |

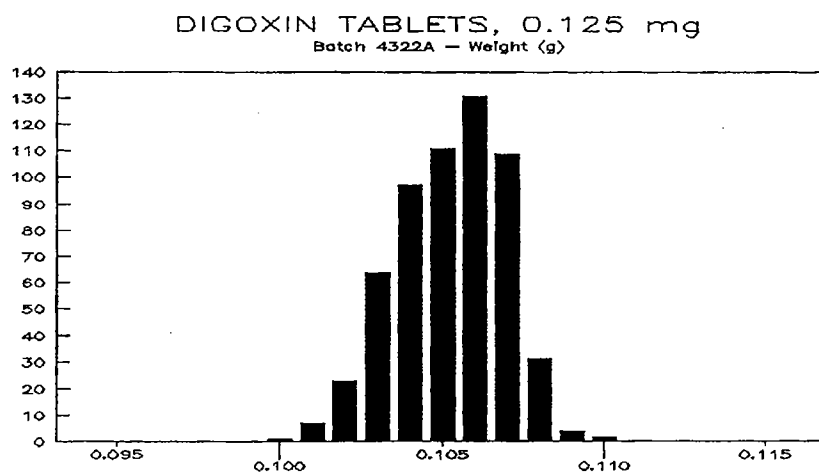
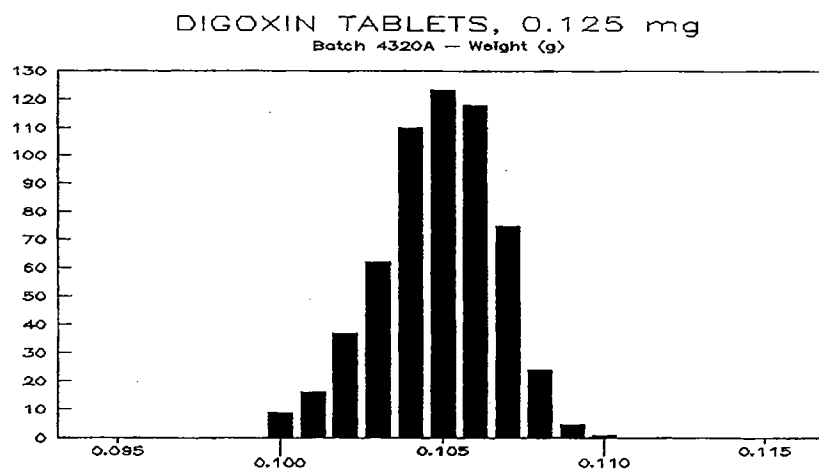
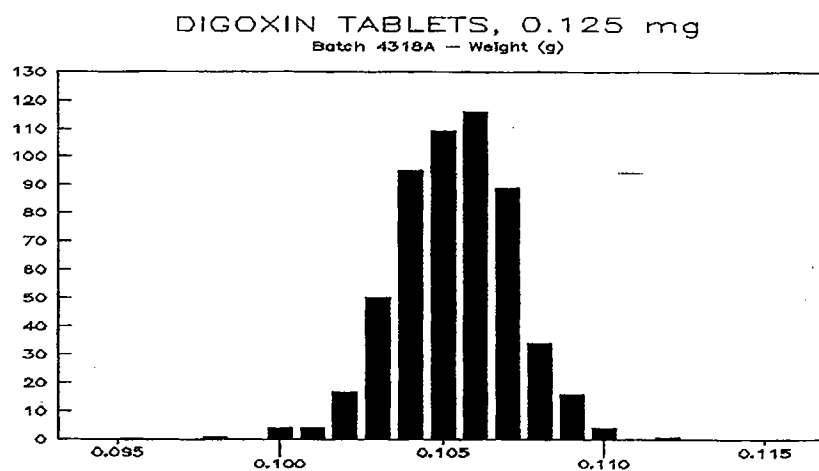
AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg - Batch # 4322A**

Compression - Weight (g) - Front

| Date | Time | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Average | St Dev. | RSD |
|----------|----------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|---------|---------|-----|
| 11/16/94 | 12:15 PM | 0.104 | 0.107 | 0.106 | 0.106 | 0.107 | 0.105 | 0.105 | 0.107 | 0.106 | 0.107 | 0.106 | 0.001 | 1.0 |
| 11/16/94 | 12:45 PM | 0.107 | 0.105 | 0.105 | 0.106 | 0.106 | 0.107 | 0.107 | 0.107 | 0.104 | 0.105 | 0.106 | 0.001 | 1.0 |
| 11/16/94 | 1:15 PM | 0.105 | 0.107 | 0.106 | 0.106 | 0.106 | 0.106 | 0.105 | 0.105 | 0.107 | 0.107 | 0.106 | 0.001 | 0.8 |
| 11/16/94 | 1:45 PM | 0.103 | 0.105 | 0.106 | 0.104 | 0.106 | 0.107 | 0.106 | 0.106 | 0.106 | 0.105 | 0.105 | 0.001 | 1.1 |
| 11/16/94 | 2:30 PM | 0.108 | 0.106 | 0.103 | 0.107 | 0.105 | 0.104 | 0.105 | 0.106 | 0.105 | 0.105 | 0.105 | 0.001 | 1.4 |
| 11/16/94 | 3:00 PM | 0.107 | 0.104 | 0.104 | 0.103 | 0.105 | 0.105 | 0.106 | 0.105 | 0.106 | 0.105 | 0.105 | 0.001 | 1.1 |
| 11/16/94 | 3:35 PM | 0.106 | 0.107 | 0.106 | 0.104 | 0.105 | 0.107 | 0.104 | 0.104 | 0.106 | 0.106 | 0.106 | 0.001 | 1.1 |
| 11/16/94 | 4:05 PM | 0.106 | 0.104 | 0.107 | 0.105 | 0.105 | 0.106 | 0.105 | 0.105 | 0.103 | 0.106 | 0.105 | 0.001 | 1.1 |
| 11/16/94 | 4:35 PM | 0.108 | 0.104 | 0.106 | 0.106 | 0.106 | 0.105 | 0.105 | 0.104 | 0.105 | 0.107 | 0.106 | 0.001 | 1.2 |
| 11/16/94 | 5:05 PM | 0.105 | 0.106 | 0.107 | 0.105 | 0.104 | 0.106 | 0.104 | 0.106 | 0.104 | 0.105 | 0.105 | 0.001 | 1.0 |
| 11/17/94 | 8:00 AM | 0.106 | 0.106 | 0.106 | 0.107 | 0.107 | 0.105 | 0.106 | 0.106 | 0.107 | 0.105 | 0.106 | 0.001 | 0.7 |
| 11/17/94 | 8:30 AM | 0.107 | 0.108 | 0.106 | 0.105 | 0.107 | 0.104 | 0.108 | 0.107 | 0.108 | 0.107 | 0.107 | 0.001 | 1.3 |
| 11/17/94 | 9:00 AM | 0.103 | 0.105 | 0.104 | 0.105 | 0.105 | 0.106 | 0.107 | 0.103 | 0.104 | 0.107 | 0.105 | 0.001 | 1.4 |
| 11/17/94 | 9:30 AM | 0.105 | 0.105 | 0.106 | 0.106 | 0.105 | 0.106 | 0.105 | 0.106 | 0.105 | 0.105 | 0.105 | 0.001 | 0.5 |
| 11/17/94 | 10:00 AM | 0.102 | 0.106 | 0.107 | 0.107 | 0.104 | 0.105 | 0.104 | 0.104 | 0.104 | 0.103 | 0.105 | 0.002 | 1.6 |
| 11/17/94 | 10:30 AM | 0.103 | 0.105 | 0.104 | 0.104 | 0.104 | 0.106 | 0.100 | 0.103 | 0.106 | 0.105 | 0.104 | 0.002 | 1.7 |
| 11/17/94 | 11:35 AM | 0.106 | 0.104 | 0.105 | 0.106 | 0.106 | 0.107 | 0.103 | 0.106 | 0.104 | 0.105 | 0.105 | 0.001 | 1.2 |
| 11/17/94 | 12:05 PM | 0.104 | 0.103 | 0.103 | 0.105 | 0.103 | 0.103 | 0.107 | 0.106 | 0.103 | 0.106 | 0.104 | 0.002 | 1.5 |
| 11/17/94 | 12:35 PM | 0.105 | 0.105 | 0.105 | 0.106 | 0.108 | 0.105 | 0.105 | 0.104 | 0.105 | 0.107 | 0.106 | 0.001 | 1.1 |
| 11/17/94 | 1:45 PM | 0.104 | 0.103 | 0.106 | 0.107 | 0.106 | 0.102 | 0.109 | 0.106 | 0.104 | 0.102 | 0.105 | 0.002 | 2.2 |
| 11/17/94 | 2:35 PM | 0.105 | 0.106 | 0.105 | 0.105 | 0.108 | 0.105 | 0.105 | 0.105 | 0.104 | 0.104 | 0.105 | 0.001 | 1.1 |
| 11/17/94 | 3:05 PM | 0.105 | 0.103 | 0.106 | 0.106 | 0.106 | 0.103 | 0.104 | 0.107 | 0.105 | 0.105 | 0.105 | 0.001 | 1.3 |
| 11/17/94 | 3:30 PM | 0.105 | 0.106 | 0.106 | 0.103 | 0.106 | 0.104 | 0.104 | 0.104 | 0.107 | 0.105 | 0.105 | 0.001 | 1.2 |
| 11/17/94 | 4:00 PM | 0.106 | 0.105 | 0.105 | 0.104 | 0.105 | 0.105 | 0.106 | 0.104 | 0.108 | 0.103 | 0.106 | 0.002 | 1.7 |
| 11/17/94 | 4:30 PM | 0.107 | 0.104 | 0.108 | 0.107 | 0.107 | 0.106 | 0.104 | 0.108 | 0.103 | 0.106 | 0.106 | 0.001 | 1.0 |
| 11/17/94 | 5:05 PM | 0.105 | 0.105 | 0.104 | 0.107 | 0.106 | 0.106 | 0.105 | 0.104 | 0.107 | 0.106 | 0.106 | 0.001 | 1.0 |
| 11/17/94 | 5:35 PM | 0.105 | 0.103 | 0.103 | 0.106 | 0.106 | 0.105 | 0.106 | 0.105 | 0.105 | 0.105 | 0.105 | 0.001 | 1.2 |
| 11/17/94 | 6:25 PM | 0.104 | 0.106 | 0.107 | 0.107 | 0.104 | 0.105 | 0.105 | 0.104 | 0.105 | 0.105 | 0.105 | 0.001 | 1.1 |
| 11/17/94 | 6:55 PM | 0.107 | 0.104 | 0.105 | 0.107 | 0.104 | 0.103 | 0.106 | 0.106 | 0.104 | 0.104 | 0.105 | 0.001 | 1.3 |

Compression - Weight (g) - Rear

| Date | Time | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Average | St Dev. | RSD |
|----------|----------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|---------|---------|-----|
| 11/16/94 | 12:15 PM | 0.107 | 0.107 | 0.104 | 0.107 | 0.105 | 0.106 | 0.108 | 0.107 | 0.104 | 0.106 | 0.106 | 0.001 | 1.3 |
| 11/16/94 | 12:45 PM | 0.107 | 0.108 | 0.107 | 0.107 | 0.105 | 0.104 | 0.106 | 0.105 | 0.103 | 0.104 | 0.106 | 0.002 | 1.6 |
| 11/16/94 | 1:15 PM | 0.104 | 0.103 | 0.104 | 0.107 | 0.107 | 0.104 | 0.104 | 0.107 | 0.106 | 0.104 | 0.105 | 0.002 | 1.5 |
| 11/16/94 | 1:45 PM | 0.104 | 0.107 | 0.106 | 0.104 | 0.106 | 0.107 | 0.104 | 0.106 | 0.106 | 0.107 | 0.106 | 0.001 | 1.2 |
| 11/16/94 | 2:30 PM | 0.106 | 0.107 | 0.108 | 0.107 | 0.103 | 0.109 | 0.106 | 0.102 | 0.105 | 0.104 | 0.106 | 0.002 | 2.1 |
| 11/16/94 | 3:00 PM | 0.107 | 0.103 | 0.110 | 0.106 | 0.107 | 0.105 | 0.108 | 0.107 | 0.108 | 0.103 | 0.106 | 0.002 | 2.1 |
| 11/16/94 | 3:35 PM | 0.107 | 0.105 | 0.106 | 0.108 | 0.102 | 0.104 | 0.102 | 0.106 | 0.103 | 0.108 | 0.105 | 0.002 | 2.2 |
| 11/16/94 | 4:05 PM | 0.101 | 0.106 | 0.102 | 0.107 | 0.102 | 0.106 | 0.104 | 0.108 | 0.106 | 0.105 | 0.105 | 0.002 | 2.3 |
| 11/16/94 | 4:35 PM | 0.107 | 0.104 | 0.102 | 0.104 | 0.103 | 0.106 | 0.105 | 0.104 | 0.103 | 0.102 | 0.104 | 0.002 | 1.6 |
| 11/16/94 | 5:05 PM | 0.103 | 0.106 | 0.105 | 0.104 | 0.103 | 0.107 | 0.103 | 0.106 | 0.106 | 0.105 | 0.105 | 0.001 | 1.4 |
| 11/17/94 | 8:00 AM | 0.106 | 0.108 | 0.106 | 0.107 | 0.108 | 0.105 | 0.107 | 0.110 | 0.109 | 0.107 | 0.107 | 0.001 | 1.4 |
| 11/17/94 | 8:30 AM | 0.104 | 0.107 | 0.103 | 0.108 | 0.107 | 0.109 | 0.104 | 0.106 | 0.108 | 0.105 | 0.106 | 0.002 | 1.9 |
| 11/17/94 | 9:00 AM | 0.105 | 0.107 | 0.106 | 0.102 | 0.103 | 0.104 | 0.104 | 0.103 | 0.105 | 0.103 | 0.105 | 0.002 | 1.5 |
| 11/17/94 | 9:30 AM | 0.102 | 0.103 | 0.105 | 0.107 | 0.106 | 0.107 | 0.107 | 0.106 | 0.103 | 0.105 | 0.105 | 0.002 | 1.8 |
| 11/17/94 | 10:00 AM | 0.103 | 0.107 | 0.107 | 0.105 | 0.107 | 0.104 | 0.106 | 0.103 | 0.104 | 0.107 | 0.105 | 0.002 | 1.6 |
| 11/17/94 | 10:30 AM | 0.108 | 0.102 | 0.106 | 0.107 | 0.107 | 0.104 | 0.103 | 0.103 | 0.103 | 0.107 | 0.105 | 0.002 | 2.1 |
| 11/17/94 | 11:35 AM | 0.104 | 0.106 | 0.106 | 0.101 | 0.108 | 0.102 | 0.107 | 0.106 | 0.103 | 0.103 | 0.105 | 0.002 | 2.2 |
| 11/17/94 | 12:05 PM | 0.107 | 0.106 | 0.104 | 0.104 | 0.107 | 0.104 | 0.107 | 0.107 | 0.102 | 0.103 | 0.105 | 0.002 | 1.8 |
| 11/17/94 | 12:35 PM | 0.101 | 0.107 | 0.102 | 0.102 | 0.107 | 0.101 | 0.105 | 0.107 | 0.102 | 0.105 | 0.104 | 0.003 | 2.5 |
| 11/17/94 | 1:45 PM | 0.106 | 0.107 | 0.103 | 0.106 | 0.104 | 0.102 | 0.107 | 0.106 | 0.104 | 0.103 | 0.105 | 0.002 | 1.7 |
| 11/17/94 | 2:35 PM | 0.103 | 0.103 | 0.105 | 0.106 | 0.107 | 0.108 | 0.105 | 0.105 | 0.106 | 0.107 | 0.106 | 0.002 | 1.6 |
| 11/17/94 | 3:05 PM | 0.106 | 0.106 | 0.102 | 0.104 | 0.103 | 0.104 | 0.105 | 0.107 | 0.103 | 0.106 | 0.105 | 0.002 | 1.6 |
| 11/17/94 | 3:30 PM | 0.102 | 0.104 | 0.105 | 0.106 | 0.107 | 0.105 | 0.107 | 0.104 | 0.106 | 0.106 | 0.105 | 0.002 | 1.5 |
| 11/17/94 | 4:00 PM | 0.107 | 0.103 | 0.104 | 0.104 | 0.108 | 0.103 | 0.107 | 0.106 | 0.105 | 0.104 | 0.105 | 0.002 | 1.7 |
| 11/17/94 | 4:30 PM | 0.106 | 0.107 | 0.103 | 0.104 | 0.104 | 0.105 | 0.104 | 0.103 | 0.106 | 0.104 | 0.105 | 0.001 | 1.3 |
| 11/17/94 | 5:05 PM | 0.105 | 0.104 | 0.107 | 0.108 | 0.106 | 0.104 | 0.101 | 0.108 | 0.106 | 0.107 | 0.106 | 0.002 | 2.1 |
| 11/17/94 | 5:35 PM | 0.103 | 0.106 | 0.103 | 0.106 | 0.107 | 0.102 | 0.102 | 0.104 | 0.105 | 0.108 | 0.105 | 0.002 | 2.0 |
| 11/17/94 | 6:25 PM | 0.101 | 0.108 | 0.106 | 0.107 | 0.103 | 0.107 | 0.108 | 0.105 | 0.107 | 0.105 | 0.106 | 0.002 | 2.1 |
| 11/17/94 | 6:55 PM | 0.103 | 0.108 | 0.101 | 0.106 | 0.107 | 0.104 | 0.106 | 0.106 | 0.103 | 0.106 | 0.105 | 0.002 | 2.1 |



AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg - Batch # 4318A**

Compression - Hardness (kp) - Front

| Date | Time | 1 | 2 | 3 | 4 | 5 | Average | St Dev. | RSD |
|----------|----------|-----|-----|-----|-----|-----|---------|---------|------|
| 11/11/94 | 1:50 PM | 4.2 | 3.8 | 5.0 | 4.5 | 4.5 | 4.4 | 0.4 | 10.0 |
| 11/11/94 | 2:45 PM | 4.1 | 4.5 | 5.0 | 4.4 | 4.3 | 4.5 | 0.3 | 7.5 |
| 11/11/94 | 3:20 PM | 4.4 | 4.6 | 4.6 | 4.6 | 4.7 | 4.6 | 0.1 | 2.4 |
| 11/11/94 | 4:00 PM | 4.4 | 4.6 | 4.7 | 4.6 | 4.7 | 4.6 | 0.1 | 2.7 |
| 11/11/94 | 4:30 PM | 5.1 | 4.6 | 4.5 | 5.0 | 5.2 | 4.9 | 0.3 | 6.4 |
| 11/12/94 | 7:25 AM | 4.6 | 4.5 | 4.2 | 4.7 | 4.6 | 4.5 | 0.2 | 4.3 |
| 11/12/94 | 7:55 AM | 4.4 | 5.1 | 4.7 | 4.8 | 4.5 | 4.7 | 0.3 | 5.8 |
| 11/12/94 | 8:25 AM | 4.4 | 4.5 | 4.2 | 5.2 | 3.9 | 4.4 | 0.5 | 10.9 |
| 11/12/94 | 8:55 AM | 4.8 | 4.7 | 4.5 | 4.3 | 4.6 | 4.6 | 0.2 | 4.2 |
| 11/12/94 | 9:25 AM | 4.6 | 4.3 | 4.8 | 4.3 | 4.5 | 4.5 | 0.2 | 4.7 |
| 11/12/94 | 9:55 AM | 4.8 | 4.5 | 4.2 | 4.2 | 4.3 | 4.4 | 0.3 | 5.8 |
| 11/12/94 | 10:25 AM | 4.8 | 4.9 | 4.5 | 4.4 | 4.4 | 4.6 | 0.2 | 5.1 |
| 11/12/94 | 11:50 AM | 4.7 | 4.8 | 4.2 | 4.2 | 4.5 | 4.5 | 0.3 | 6.2 |
| 11/12/94 | 12:20 PM | 5.0 | 4.4 | 4.8 | 4.2 | 4.7 | 4.6 | 0.3 | 6.9 |
| 11/12/94 | 12:50 PM | 4.8 | 4.5 | 4.6 | 4.4 | 4.2 | 4.5 | 0.2 | 5.0 |
| 11/12/94 | 1:20 PM | 4.7 | 4.6 | 4.9 | 4.4 | 4.1 | 4.5 | 0.3 | 6.7 |
| 11/12/94 | 1:50 PM | 4.5 | 4.5 | 4.7 | 4.5 | 4.7 | 4.6 | 0.1 | 2.4 |
| 11/12/94 | 2:20 PM | 4.4 | 4.6 | 4.4 | 5.1 | 5.0 | 4.7 | 0.3 | 7.1 |
| 11/14/94 | 8:20 AM | 4.0 | 3.9 | 3.7 | 4.3 | 4.1 | 4.0 | 0.2 | 5.6 |
| 11/14/94 | 8:45 AM | 4.2 | 4.3 | 4.2 | 4.2 | 4.0 | 4.2 | 0.1 | 2.6 |
| 11/14/94 | 9:15 AM | 4.3 | 4.2 | 4.4 | 4.3 | 4.6 | 4.4 | 0.2 | 3.5 |
| 11/14/94 | 9:45 AM | 4.4 | 4.0 | 3.9 | 4.4 | 4.4 | 4.2 | 0.2 | 5.9 |
| 11/14/94 | 10:15 AM | 4.3 | 4.3 | 4.2 | 4.3 | 3.9 | 4.2 | 0.2 | 4.1 |
| 11/14/94 | 10:45 AM | 4.4 | 4.7 | 4.5 | 4.3 | 4.6 | 4.5 | 0.2 | 3.5 |
| 11/14/94 | 1:25 PM | 3.9 | 4.4 | 4.0 | 4.1 | 4.3 | 4.1 | 0.2 | 5.0 |
| 11/14/94 | 1:50 PM | 4.0 | 4.9 | 4.2 | 4.3 | 4.3 | 4.3 | 0.3 | 7.7 |
| 11/14/94 | 2:45 PM | 4.3 | 4.5 | 4.7 | 3.7 | 4.6 | 4.4 | 0.4 | 9.1 |

Compression - Hardness (kp) - Rear

| Date | Time | 1 | 2 | 3 | 4 | 5 | Average | St Dev. | RSD |
|----------|----------|-----|-----|-----|-----|-----|---------|---------|------|
| 11/11/94 | 1:50 PM | 4.5 | 3.6 | 4.3 | 4.6 | 4.2 | 4.2 | 0.4 | 9.2 |
| 11/11/94 | 2:45 PM | 4.3 | 3.7 | 4.5 | 4.6 | 4.6 | 4.3 | 0.4 | 8.7 |
| 11/11/94 | 3:20 PM | 4.5 | 4.9 | 4.1 | 4.7 | 4.9 | 4.6 | 0.3 | 7.2 |
| 11/11/94 | 4:00 PM | 4.8 | 3.9 | 4.4 | 4.0 | 5.0 | 4.4 | 0.5 | 10.9 |
| 11/11/94 | 4:30 PM | 4.5 | 4.0 | 4.2 | 4.5 | 4.6 | 4.4 | 0.3 | 5.8 |
| 11/12/94 | 7:25 AM | 4.7 | 5.1 | 4.4 | 4.7 | 5.4 | 4.9 | 0.4 | 8.0 |
| 11/12/94 | 7:55 AM | 4.4 | 4.2 | 4.4 | 4.6 | 4.4 | 4.4 | 0.1 | 3.2 |
| 11/12/94 | 8:25 AM | 3.9 | 5.0 | 4.3 | 5.3 | 3.7 | 4.4 | 0.7 | 15.6 |
| 11/12/94 | 8:55 AM | 4.5 | 5.3 | 4.1 | 5.0 | 4.7 | 4.7 | 0.5 | 9.8 |
| 11/12/94 | 9:25 AM | 4.4 | 4.1 | 4.5 | 5.3 | 4.1 | 4.5 | 0.5 | 11.0 |
| 11/12/94 | 9:55 AM | 4.6 | 5.4 | 4.4 | 4.6 | 5.1 | 4.8 | 0.4 | 8.6 |
| 11/12/94 | 10:25 AM | 4.6 | 5.0 | 4.7 | 4.1 | 3.8 | 4.4 | 0.5 | 10.9 |
| 11/12/94 | 11:50 AM | 5.0 | 4.1 | 4.3 | 4.2 | 4.7 | 4.5 | 0.4 | 8.5 |
| 11/12/94 | 12:20 PM | 5.4 | 5.0 | 4.3 | 4.2 | 4.2 | 4.6 | 0.5 | 11.9 |
| 11/12/94 | 12:50 PM | 4.5 | 4.4 | 4.6 | 5.4 | 4.6 | 4.7 | 0.4 | 8.5 |
| 11/12/94 | 1:20 PM | 5.0 | 4.5 | 5.0 | 4.6 | 4.4 | 4.7 | 0.3 | 6.0 |
| 11/12/94 | 1:50 PM | 4.6 | 4.4 | 5.1 | 5.0 | 4.9 | 4.8 | 0.3 | 6.1 |
| 11/12/94 | 2:20 PM | 5.2 | 4.4 | 4.2 | 4.4 | 5.0 | 4.6 | 0.4 | 9.3 |
| 11/14/94 | 8:20 AM | 4.8 | 4.0 | 4.2 | 4.0 | 4.3 | 4.3 | 0.3 | 7.7 |
| 11/14/94 | 8:45 AM | 4.0 | 4.5 | 4.0 | 4.0 | 4.4 | 4.2 | 0.2 | 6.0 |
| 11/14/94 | 9:15 AM | 4.3 | 4.5 | 4.5 | 4.6 | 4.5 | 4.5 | 0.1 | 2.4 |
| 11/14/94 | 9:45 AM | 4.8 | 4.6 | 4.6 | 4.6 | 4.5 | 4.6 | 0.1 | 2.4 |
| 11/14/94 | 10:15 AM | 4.2 | 4.5 | 4.7 | 4.9 | 4.3 | 4.5 | 0.3 | 6.3 |
| 11/14/94 | 10:45 AM | 4.1 | 4.4 | 4.2 | 4.2 | 3.9 | 4.2 | 0.2 | 4.4 |
| 11/14/94 | 1:25 PM | 4.4 | 4.2 | 3.8 | 4.2 | 4.3 | 4.2 | 0.2 | 5.5 |
| 11/14/94 | 1:50 PM | 4.5 | 4.1 | 4.7 | 4.9 | 4.2 | 4.5 | 0.3 | 7.5 |
| 11/14/94 | 2:45 PM | 3.7 | 4.7 | 3.6 | 4.4 | 4.4 | 4.2 | 0.5 | 11.6 |

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg - Batch # 4320A**

Compression - Hardness (kp) - Front

| Date | Time | 1 | 2 | 3 | 4 | 5 | Average | St Dev. | RSD |
|----------|----------|-----|-----|-----|-----|-----|---------|---------|-----|
| 11/14/94 | 5:15 PM | 4.4 | 4.7 | 4.8 | 4.4 | 4.4 | 4.5 | 0.2 | 4.3 |
| 11/14/94 | 5:45 PM | 4.6 | 4.1 | 4.7 | 4.3 | 4.3 | 4.4 | 0.2 | 5.6 |
| 11/14/94 | 6:15 PM | 4.6 | 5.0 | 4.5 | 4.9 | 4.3 | 4.7 | 0.3 | 6.2 |
| 11/14/94 | 6:45 PM | 4.2 | 4.3 | 4.5 | 4.2 | 4.2 | 4.3 | 0.1 | 3.0 |
| 11/14/94 | 7:15 PM | 4.3 | 4.6 | 4.0 | 4.2 | 4.6 | 4.3 | 0.3 | 6.0 |
| 11/14/94 | 7:45 PM | 5.2 | 4.5 | 4.2 | 5.0 | 4.6 | 4.7 | 0.4 | 8.5 |
| 11/14/94 | 8:15 PM | 4.7 | 4.6 | 5.0 | 4.2 | 4.8 | 4.7 | 0.3 | 6.4 |
| 11/14/94 | 8:45 PM | 5.3 | 4.8 | 4.7 | 5.7 | 4.5 | 5.0 | 0.5 | 9.8 |
| 11/15/94 | 8:00 AM | 4.5 | 4.6 | 4.3 | 4.3 | 4.7 | 4.5 | 0.2 | 4.0 |
| 11/15/94 | 8:30 AM | 4.6 | 4.3 | 4.4 | 4.8 | 4.3 | 4.5 | 0.2 | 4.8 |
| 11/15/94 | 9:00 AM | 4.7 | 4.5 | 4.4 | 4.3 | 4.4 | 4.5 | 0.2 | 3.4 |
| 11/15/94 | 9:30 AM | 4.5 | 4.8 | 4.5 | 4.5 | 4.5 | 4.6 | 0.1 | 2.9 |
| 11/15/94 | 10:00 AM | 4.6 | 4.2 | 4.6 | 5.0 | 4.3 | 4.5 | 0.3 | 6.9 |
| 11/15/94 | 10:30 AM | 4.2 | 4.9 | 4.8 | 5.1 | 4.8 | 4.8 | 0.3 | 7.1 |
| 11/15/94 | 11:35 AM | 4.4 | 4.9 | 4.2 | 4.4 | 4.6 | 4.5 | 0.3 | 5.9 |
| 11/15/94 | 12:05 PM | 4.2 | 4.3 | 4.2 | 4.8 | 4.5 | 4.4 | 0.3 | 5.8 |
| 11/15/94 | 12:35 PM | 4.0 | 4.7 | 4.2 | 4.2 | 3.9 | 4.2 | 0.3 | 7.3 |
| 11/15/94 | 1:05 PM | 4.6 | 4.6 | 4.5 | 4.4 | 4.8 | 4.6 | 0.1 | 3.2 |
| 11/15/94 | 1:35 PM | 4.4 | 4.6 | 4.7 | 5.3 | 4.9 | 4.8 | 0.3 | 7.2 |
| 11/15/94 | 4:30 PM | 4.7 | 4.3 | 4.3 | 5.0 | 4.5 | 4.6 | 0.3 | 6.5 |
| 11/15/94 | 5:00 PM | 4.3 | 4.4 | 4.8 | 4.3 | 4.3 | 4.4 | 0.2 | 4.9 |
| 11/15/94 | 5:30 PM | 4.7 | 4.5 | 5.2 | 4.5 | 4.8 | 4.7 | 0.3 | 6.1 |
| 11/15/94 | 6:10 PM | 4.7 | 4.2 | 4.4 | 4.8 | 4.8 | 4.6 | 0.3 | 5.9 |
| 11/15/94 | 6:40 PM | 4.5 | 4.3 | 4.4 | 4.8 | 4.3 | 4.5 | 0.2 | 4.6 |
| 11/15/94 | 7:10 PM | 4.6 | 4.4 | 4.7 | 4.4 | 4.3 | 4.5 | 0.2 | 3.7 |
| 11/15/94 | 7:40 PM | 4.8 | 4.3 | 4.8 | 4.3 | 4.4 | 4.5 | 0.3 | 5.7 |
| 11/15/94 | 8:10 PM | 4.7 | 4.2 | 4.0 | 4.5 | 4.4 | 4.4 | 0.3 | 6.2 |
| 11/15/94 | 8:40 PM | 4.7 | 5.2 | 4.4 | 5.0 | 4.6 | 4.8 | 0.3 | 6.7 |
| 11/15/94 | 9:10 PM | 4.8 | 4.6 | 5.1 | 4.1 | 4.5 | 4.6 | 0.4 | 8.0 |

Compression - Hardness (kp) - Rear

| Date | Time | 1 | 2 | 3 | 4 | 5 | Average | St Dev. | RSD |
|----------|----------|-----|-----|-----|-----|-----|---------|---------|------|
| 11/14/94 | 5:15 PM | 3.9 | 3.9 | 3.7 | 4.4 | 4.7 | 4.1 | 0.4 | 10.1 |
| 11/14/94 | 5:45 PM | 4.1 | 4.2 | 4.9 | 4.6 | 4.1 | 4.4 | 0.4 | 8.1 |
| 11/14/94 | 6:15 PM | 4.3 | 4.6 | 3.9 | 4.7 | 3.4 | 4.2 | 0.5 | 12.8 |
| 11/14/94 | 6:45 PM | 4.1 | 3.9 | 3.7 | 4.0 | 4.1 | 4.0 | 0.2 | 4.2 |
| 11/14/94 | 7:15 PM | 4.7 | 4.0 | 3.9 | 4.6 | 4.2 | 4.3 | 0.4 | 8.3 |
| 11/14/94 | 7:45 PM | 4.8 | 4.4 | 4.5 | 4.7 | 4.7 | 4.6 | 0.2 | 3.6 |
| 11/14/94 | 8:15 PM | 5.4 | 5.8 | 4.3 | 5.6 | 4.9 | 5.2 | 0.6 | 11.6 |
| 11/14/94 | 8:45 PM | 5.3 | 5.4 | 4.3 | 4.9 | 4.8 | 4.9 | 0.4 | 8.9 |
| 11/15/94 | 8:00 AM | 4.2 | 3.7 | 4.4 | 4.8 | 4.9 | 4.4 | 0.5 | 11.0 |
| 11/15/94 | 8:30 AM | 3.7 | 3.9 | 3.8 | 3.9 | 4.9 | 4.0 | 0.5 | 12.1 |
| 11/15/94 | 9:00 AM | 4.8 | 4.2 | 3.9 | 4.5 | 4.8 | 4.4 | 0.4 | 8.8 |
| 11/15/94 | 9:30 AM | 4.1 | 4.6 | 4.7 | 4.9 | 4.0 | 4.5 | 0.4 | 8.8 |
| 11/15/94 | 10:00 AM | 4.5 | 4.2 | 4.2 | 4.2 | 4.1 | 4.2 | 0.2 | 3.6 |
| 11/15/94 | 10:30 AM | 4.6 | 4.7 | 4.9 | 5.0 | 4.5 | 4.7 | 0.2 | 4.4 |
| 11/15/94 | 11:35 AM | 3.7 | 4.1 | 4.7 | 4.1 | 4.6 | 4.2 | 0.4 | 9.7 |
| 11/15/94 | 12:05 PM | 4.8 | 4.4 | 4.8 | 4.3 | 3.9 | 4.4 | 0.4 | 8.5 |
| 11/15/94 | 12:35 PM | 4.0 | 4.5 | 4.1 | 4.7 | 5.0 | 4.5 | 0.4 | 9.3 |
| 11/15/94 | 1:05 PM | 4.3 | 4.5 | 4.8 | 4.4 | 4.7 | 4.5 | 0.2 | 4.6 |
| 11/15/94 | 1:35 PM | 4.7 | 4.7 | 4.0 | 4.6 | 4.7 | 4.5 | 0.3 | 6.7 |
| 11/15/94 | 4:30 PM | 4.2 | 4.1 | 4.7 | 4.3 | 4.2 | 4.3 | 0.2 | 5.5 |
| 11/15/94 | 5:00 PM | 4.8 | 4.7 | 5.2 | 4.6 | 4.9 | 4.8 | 0.2 | 4.8 |
| 11/15/94 | 5:30 PM | 5.1 | 4.3 | 4.5 | 4.1 | 4.7 | 4.5 | 0.4 | 8.5 |
| 11/15/94 | 6:10 PM | 4.4 | 4.9 | 4.6 | 4.4 | 4.4 | 4.5 | 0.2 | 4.8 |
| 11/15/94 | 6:40 PM | 4.7 | 5.1 | 4.8 | 4.1 | 4.2 | 4.6 | 0.4 | 9.2 |
| 11/15/94 | 7:10 PM | 3.9 | 4.8 | 4.6 | 3.7 | 5.0 | 4.4 | 0.6 | 13.0 |
| 11/15/94 | 7:40 PM | 4.8 | 4.4 | 4.7 | 4.7 | 5.2 | 4.8 | 0.3 | 6.1 |
| 11/15/94 | 8:10 PM | 4.9 | 4.4 | 4.0 | 4.7 | 4.5 | 4.5 | 0.3 | 7.5 |
| 11/15/94 | 8:40 PM | 5.2 | 4.1 | 4.6 | 4.5 | 5.2 | 4.7 | 0.5 | 10.1 |
| 11/15/94 | 9:10 PM | 4.0 | 4.0 | 4.5 | 5.2 | 4.7 | 4.5 | 0.5 | 11.3 |

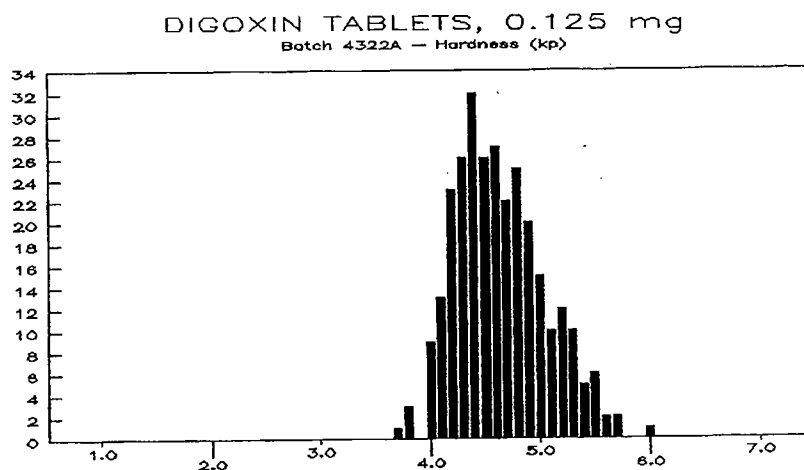
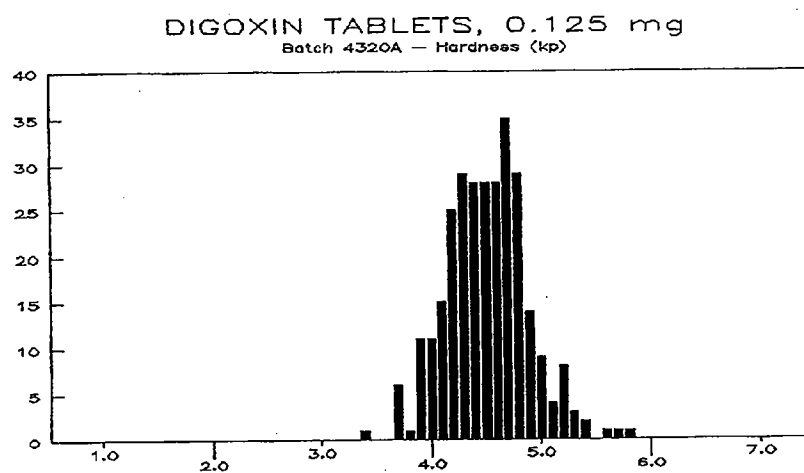
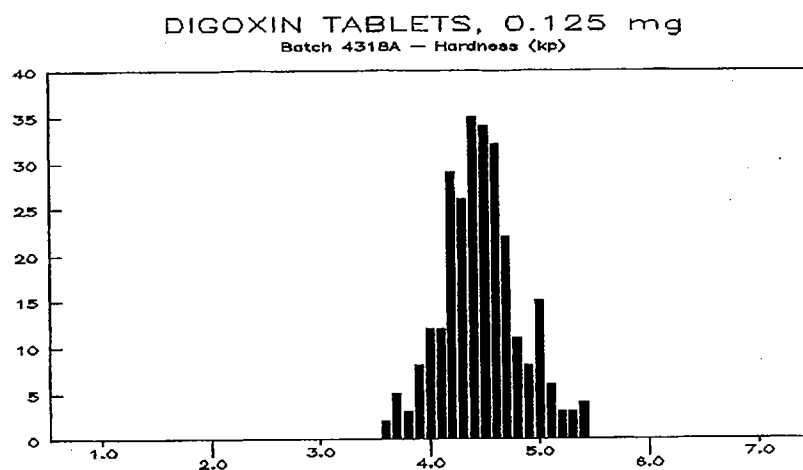
AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg - Batch # 4322A**

Compression - Hardness (kp) - Front

| Date | Time | 1 | 2 | 3 | 4 | 5 | Average | St Dev. | RSD |
|----------|----------|-----|-----|-----|-----|-----|---------|---------|------|
| 11/16/94 | 12:15 PM | 4.8 | 4.8 | 4.5 | 4.9 | 4.4 | 4.7 | 0.2 | 4.6 |
| 11/16/94 | 12:45 PM | 4.6 | 4.8 | 4.3 | 4.3 | 4.4 | 4.5 | 0.2 | 4.8 |
| 11/16/94 | 1:15 PM | 4.7 | 4.3 | 4.8 | 4.5 | 4.2 | 4.5 | 0.3 | 5.7 |
| 11/16/94 | 1:45 PM | 4.2 | 4.7 | 4.4 | 4.9 | 4.7 | 4.6 | 0.3 | 6.1 |
| 11/16/94 | 2:30 PM | 4.5 | 5.3 | 4.7 | 4.5 | 5.2 | 4.8 | 0.4 | 7.9 |
| 11/16/94 | 3:00 PM | 4.6 | 4.6 | 4.3 | 4.6 | 5.2 | 4.7 | 0.3 | 7.1 |
| 11/16/94 | 3:35 PM | 4.2 | 4.5 | 5.2 | 4.8 | 4.7 | 4.7 | 0.4 | 7.9 |
| 11/16/94 | 4:05 PM | 4.7 | 4.8 | 4.4 | 4.7 | 5.1 | 4.7 | 0.3 | 5.3 |
| 11/16/94 | 4:35 PM | 4.5 | 4.8 | 4.5 | 4.4 | 4.5 | 4.5 | 0.2 | 3.3 |
| 11/16/94 | 5:05 PM | 4.6 | 4.8 | 5.0 | 4.0 | 4.9 | 4.7 | 0.4 | 8.5 |
| 11/17/94 | 8:00 AM | 4.2 | 4.4 | 4.3 | 4.5 | 4.3 | 4.3 | 0.1 | 2.6 |
| 11/17/94 | 8:30 AM | 4.5 | 4.9 | 4.3 | 4.8 | 4.4 | 4.6 | 0.3 | 5.7 |
| 11/17/94 | 9:00 AM | 4.1 | 4.4 | 4.5 | 4.3 | 4.4 | 4.3 | 0.2 | 3.5 |
| 11/17/94 | 9:30 AM | 4.8 | 4.6 | 4.6 | 4.4 | 4.9 | 4.7 | 0.2 | 4.2 |
| 11/17/94 | 10:00 AM | 4.1 | 4.4 | 4.0 | 4.7 | 4.6 | 4.4 | 0.3 | 7.0 |
| 11/17/94 | 10:30 AM | 4.6 | 4.6 | 4.9 | 4.0 | 4.3 | 4.5 | 0.3 | 7.6 |
| 11/17/94 | 11:35 AM | 4.4 | 4.6 | 4.4 | 4.8 | 5.3 | 4.7 | 0.4 | 8.0 |
| 11/17/94 | 12:05 PM | 4.1 | 4.0 | 4.7 | 4.5 | 4.1 | 4.3 | 0.3 | 7.1 |
| 11/17/94 | 12:35 PM | 4.6 | 4.2 | 4.2 | 4.2 | 5.0 | 4.4 | 0.4 | 8.1 |
| 11/17/94 | 1:45 PM | 4.0 | 5.3 | 5.4 | 5.3 | 4.3 | 4.9 | 0.7 | 13.5 |
| 11/17/94 | 2:35 PM | 4.1 | 4.3 | 4.2 | 4.2 | 4.6 | 4.3 | 0.2 | 4.5 |
| 11/17/94 | 3:05 PM | 4.0 | 4.3 | 4.9 | 4.5 | 4.1 | 4.4 | 0.4 | 8.2 |
| 11/17/94 | 3:30 PM | 4.2 | 4.2 | 4.2 | 4.3 | 4.0 | 4.2 | 0.1 | 2.6 |
| 11/17/94 | 4:00 PM | 4.1 | 4.2 | 4.3 | 4.4 | 4.5 | 4.3 | 0.2 | 3.7 |
| 11/17/94 | 4:30 PM | 5.0 | 4.4 | 5.0 | 4.7 | 4.8 | 4.8 | 0.2 | 5.2 |
| 11/17/94 | 5:05 PM | 4.4 | 4.5 | 4.5 | 4.2 | 4.9 | 4.5 | 0.3 | 5.7 |
| 11/17/94 | 5:35 PM | 4.9 | 4.1 | 4.4 | 4.4 | 4.5 | 4.5 | 0.3 | 6.5 |
| 11/17/94 | 6:25 PM | 4.0 | 5.1 | 4.5 | 4.9 | 4.4 | 4.6 | 0.4 | 9.4 |
| 11/17/94 | 6:55 PM | 4.8 | 4.3 | 4.5 | 4.8 | 5.3 | 4.7 | 0.4 | 8.0 |

Compression - Hardness (kp) - Rear

| Date | Time | 1 | 2 | 3 | 4 | 5 | Average | St Dev. | RSD |
|----------|----------|-----|-----|-----|-----|-----|---------|---------|------|
| 11/16/94 | 12:15 PM | 4.8 | 5.0 | 5.3 | 4.3 | 5.5 | 5.0 | 0.5 | 9.4 |
| 11/16/94 | 12:45 PM | 4.4 | 4.8 | 4.7 | 4.7 | 4.6 | 4.6 | 0.2 | 3.3 |
| 11/16/94 | 1:15 PM | 4.7 | 5.6 | 4.7 | 4.5 | 4.5 | 4.8 | 0.5 | 9.5 |
| 11/16/94 | 1:45 PM | 5.4 | 4.9 | 5.0 | 5.2 | 5.2 | 5.1 | 0.2 | 3.8 |
| 11/16/94 | 2:30 PM | 4.6 | 5.6 | 5.3 | 5.1 | 4.4 | 5.0 | 0.5 | 9.9 |
| 11/16/94 | 3:00 PM | 5.3 | 4.9 | 4.4 | 5.7 | 4.7 | 5.0 | 0.5 | 10.2 |
| 11/16/94 | 3:35 PM | 4.7 | 4.9 | 4.6 | 5.1 | 4.5 | 4.8 | 0.2 | 5.1 |
| 11/16/94 | 4:05 PM | 5.2 | 4.4 | 5.2 | 5.0 | 4.6 | 4.9 | 0.4 | 7.4 |
| 11/16/94 | 4:35 PM | 4.3 | 4.9 | 4.7 | 5.2 | 4.8 | 4.8 | 0.3 | 6.8 |
| 11/16/94 | 5:05 PM | 5.1 | 4.7 | 5.5 | 5.0 | 5.2 | 5.1 | 0.3 | 5.7 |
| 11/17/94 | 8:00 AM | 4.1 | 5.4 | 6.0 | 5.3 | 5.5 | 5.3 | 0.7 | 13.3 |
| 11/17/94 | 8:30 AM | 4.6 | 4.3 | 4.7 | 5.7 | 4.9 | 4.8 | 0.5 | 10.9 |
| 11/17/94 | 9:00 AM | 4.9 | 5.3 | 4.3 | 4.3 | 4.1 | 4.6 | 0.5 | 11.0 |
| 11/17/94 | 9:30 AM | 5.1 | 4.9 | 4.8 | 4.6 | 4.9 | 4.9 | 0.2 | 3.7 |
| 11/17/94 | 10:00 AM | 4.1 | 4.4 | 4.2 | 4.8 | 5.4 | 4.6 | 0.5 | 11.6 |
| 11/17/94 | 10:30 AM | 4.3 | 5.2 | 4.2 | 4.7 | 4.8 | 4.6 | 0.4 | 8.7 |
| 11/17/94 | 11:35 AM | 5.0 | 5.0 | 4.1 | 5.5 | 4.6 | 4.8 | 0.5 | 10.8 |
| 11/17/94 | 12:05 PM | 5.2 | 4.4 | 4.8 | 4.2 | 4.3 | 4.6 | 0.4 | 9.1 |
| 11/17/94 | 12:35 PM | 4.7 | 3.7 | 4.5 | 3.8 | 5.0 | 4.3 | 0.6 | 13.1 |
| 11/17/94 | 1:45 PM | 4.1 | 4.6 | 4.2 | 4.3 | 4.5 | 4.3 | 0.2 | 4.8 |
| 11/17/94 | 2:35 PM | 4.9 | 4.2 | 5.0 | 5.2 | 4.3 | 4.7 | 0.4 | 9.4 |
| 11/17/94 | 3:05 PM | 3.8 | 5.1 | 3.8 | 4.8 | 4.6 | 4.4 | 0.6 | 13.4 |
| 11/17/94 | 3:30 PM | 4.4 | 4.2 | 4.3 | 5.4 | 4.2 | 4.5 | 0.5 | 11.3 |
| 11/17/94 | 4:00 PM | 4.6 | 4.3 | 4.4 | 4.2 | 4.8 | 4.5 | 0.2 | 5.4 |
| 11/17/94 | 4:30 PM | 4.8 | 4.5 | 4.7 | 5.0 | 4.4 | 4.7 | 0.2 | 5.1 |
| 11/17/94 | 5:05 PM | 5.1 | 5.1 | 4.6 | 5.1 | 4.9 | 5.0 | 0.2 | 4.4 |
| 11/17/94 | 5:35 PM | 4.6 | 5.0 | 4.4 | 4.4 | 4.6 | 4.6 | 0.2 | 5.3 |
| 11/17/94 | 6:25 PM | 4.5 | 4.4 | 4.6 | 4.2 | 5.0 | 4.5 | 0.3 | 6.5 |
| 11/17/94 | 6:55 PM | 4.4 | 5.5 | 4.0 | 4.8 | 5.5 | 4.8 | 0.7 | 13.8 |



AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg - Batch # 4318A**

Compression - Thickness (mm) - Front

| Date | Time | 1 | 2 | 3 | 4 | 5 | Average | St Dev. | RSD |
|----------|----------|------|------|------|------|------|---------|---------|-----|
| 11/11/94 | 1:50 PM | 2.66 | 2.66 | 2.65 | 2.62 | 2.65 | 2.65 | 0.02 | 0.6 |
| 11/11/94 | 2:45 PM | 2.62 | 2.62 | 2.63 | 2.64 | 2.60 | 2.62 | 0.01 | 0.6 |
| 11/11/94 | 3:20 PM | 2.67 | 2.65 | 2.63 | 2.64 | 2.65 | 2.65 | 0.01 | 0.6 |
| 11/11/94 | 4:00 PM | 2.61 | 2.63 | 2.68 | 2.64 | 2.59 | 2.63 | 0.03 | 1.3 |
| 11/11/94 | 4:30 PM | 2.66 | 2.64 | 2.64 | 2.64 | 2.63 | 2.64 | 0.01 | 0.4 |
| 11/12/94 | 7:25 AM | 2.60 | 2.68 | 2.68 | 2.67 | 2.66 | 2.66 | 0.03 | 1.3 |
| 11/12/94 | 7:55 AM | 2.71 | 2.70 | 2.69 | 2.70 | 2.65 | 2.69 | 0.02 | 0.9 |
| 11/12/94 | 8:25 AM | 2.64 | 2.64 | 2.66 | 2.62 | 2.66 | 2.64 | 0.02 | 0.6 |
| 11/12/94 | 8:55 AM | 2.66 | 2.68 | 2.63 | 2.63 | 2.61 | 2.64 | 0.03 | 1.1 |
| 11/12/94 | 9:25 AM | 2.63 | 2.65 | 2.65 | 2.65 | 2.64 | 2.64 | 0.01 | 0.3 |
| 11/12/94 | 9:55 AM | 2.68 | 2.66 | 2.61 | 2.63 | 2.63 | 2.64 | 0.03 | 1.1 |
| 11/12/94 | 10:25 AM | 2.63 | 2.67 | 2.61 | 2.67 | 2.63 | 2.64 | 0.03 | 1.0 |
| 11/12/94 | 11:50 AM | 2.66 | 2.60 | 2.67 | 2.63 | 2.65 | 2.64 | 0.03 | 1.1 |
| 11/12/94 | 12:20 PM | 2.63 | 2.59 | 2.59 | 2.62 | 2.67 | 2.62 | 0.03 | 1.3 |
| 11/12/94 | 12:50 PM | 2.63 | 2.66 | 2.62 | 2.61 | 2.64 | 2.63 | 0.02 | 0.7 |
| 11/12/94 | 1:20 PM | 2.62 | 2.61 | 2.61 | 2.65 | 2.61 | 2.62 | 0.02 | 0.7 |
| 11/12/94 | 1:50 PM | 2.64 | 2.61 | 2.62 | 2.59 | 2.63 | 2.62 | 0.02 | 0.7 |
| 11/12/94 | 2:20 PM | 2.60 | 2.60 | 2.63 | 2.64 | 2.60 | 2.61 | 0.02 | 0.7 |
| 11/14/94 | 8:20 AM | 2.62 | 2.61 | 2.67 | 2.63 | 2.63 | 2.63 | 0.02 | 0.9 |
| 11/14/94 | 8:45 AM | 2.64 | 2.62 | 2.63 | 2.60 | 2.65 | 2.63 | 0.02 | 0.7 |
| 11/14/94 | 9:15 AM | 2.61 | 2.65 | 2.65 | 2.63 | 2.65 | 2.64 | 0.02 | 0.7 |
| 11/14/94 | 9:45 AM | 2.64 | 2.61 | 2.59 | 2.63 | 2.62 | 2.62 | 0.02 | 0.7 |
| 11/14/94 | 10:15 AM | 2.64 | 2.62 | 2.63 | 2.62 | 2.63 | 2.63 | 0.01 | 0.3 |
| 11/14/94 | 10:45 AM | 2.59 | 2.66 | 2.63 | 2.63 | 2.63 | 2.63 | 0.02 | 0.9 |
| 11/14/94 | 1:25 PM | 2.61 | 2.66 | 2.61 | 2.64 | 2.61 | 2.63 | 0.02 | 0.9 |
| 11/14/94 | 1:50 PM | 2.64 | 2.62 | 2.61 | 2.58 | 2.59 | 2.61 | 0.02 | 0.9 |
| 11/14/94 | 2:45 PM | 2.64 | 2.65 | 2.59 | 2.63 | 2.63 | 2.63 | 0.02 | 0.9 |

Compression - Thickness (mm) - Rear

| Date | Time | 1 | 2 | 3 | 4 | 5 | Average | St Dev. | RSD |
|----------|----------|------|------|------|------|------|---------|---------|-----|
| 11/11/94 | 1:50 PM | 2.57 | 2.59 | 2.63 | 2.62 | 2.64 | 2.61 | 0.03 | 1.1 |
| 11/11/94 | 2:45 PM | 2.58 | 2.63 | 2.59 | 2.64 | 2.63 | 2.61 | 0.03 | 1.0 |
| 11/11/94 | 3:20 PM | 2.61 | 2.60 | 2.64 | 2.63 | 2.64 | 2.62 | 0.02 | 0.7 |
| 11/11/94 | 4:00 PM | 2.61 | 2.65 | 2.61 | 2.62 | 2.58 | 2.61 | 0.03 | 1.0 |
| 11/11/94 | 4:30 PM | 2.62 | 2.65 | 2.55 | 2.65 | 2.62 | 2.62 | 0.04 | 1.6 |
| 11/12/94 | 7:25 AM | 2.66 | 2.64 | 2.65 | 2.67 | 2.68 | 2.66 | 0.02 | 0.6 |
| 11/12/94 | 7:55 AM | 2.60 | 2.65 | 2.66 | 2.66 | 2.63 | 2.64 | 0.03 | 1.0 |
| 11/12/94 | 8:25 AM | 2.65 | 2.64 | 2.59 | 2.68 | 2.60 | 2.63 | 0.04 | 1.4 |
| 11/12/94 | 8:55 AM | 2.67 | 2.66 | 2.66 | 2.68 | 2.65 | 2.66 | 0.01 | 0.4 |
| 11/12/94 | 9:25 AM | 2.64 | 2.58 | 2.61 | 2.61 | 2.59 | 2.61 | 0.02 | 0.9 |
| 11/12/94 | 9:55 AM | 2.62 | 2.66 | 2.68 | 2.66 | 2.62 | 2.65 | 0.03 | 1.0 |
| 11/12/94 | 10:25 AM | 2.59 | 2.60 | 2.65 | 2.63 | 2.64 | 2.62 | 0.03 | 1.0 |
| 11/12/94 | 11:50 AM | 2.68 | 2.63 | 2.66 | 2.62 | 2.66 | 2.65 | 0.02 | 0.9 |
| 11/12/94 | 12:20 PM | 2.60 | 2.63 | 2.65 | 2.63 | 2.65 | 2.63 | 0.02 | 0.8 |
| 11/12/94 | 12:50 PM | 2.64 | 2.61 | 2.67 | 2.62 | 2.61 | 2.63 | 0.03 | 1.0 |
| 11/12/94 | 1:20 PM | 2.62 | 2.63 | 2.63 | 2.61 | 2.68 | 2.63 | 0.03 | 1.0 |
| 11/12/94 | 1:50 PM | 2.64 | 2.62 | 2.63 | 2.65 | 2.65 | 2.64 | 0.01 | 0.5 |
| 11/12/94 | 2:20 PM | 2.63 | 2.60 | 2.59 | 2.63 | 2.64 | 2.62 | 0.02 | 0.8 |
| 11/14/94 | 8:20 AM | 2.64 | 2.63 | 2.61 | 2.65 | 2.66 | 2.64 | 0.02 | 0.7 |
| 11/14/94 | 8:45 AM | 2.61 | 2.64 | 2.59 | 2.63 | 2.62 | 2.62 | 0.02 | 0.7 |
| 11/14/94 | 9:15 AM | 2.63 | 2.63 | 2.64 | 2.59 | 2.65 | 2.63 | 0.02 | 0.9 |
| 11/14/94 | 9:45 AM | 2.63 | 2.66 | 2.63 | 2.63 | 2.64 | 2.64 | 0.01 | 0.5 |
| 11/14/94 | 10:15 AM | 2.60 | 2.61 | 2.63 | 2.57 | 2.60 | 2.60 | 0.02 | 0.8 |
| 11/14/94 | 10:45 AM | 2.60 | 2.57 | 2.60 | 2.58 | 2.57 | 2.58 | 0.02 | 0.6 |
| 11/14/94 | 1:25 PM | 2.64 | 2.61 | 2.62 | 2.60 | 2.65 | 2.62 | 0.02 | 0.8 |
| 11/14/94 | 1:50 PM | 2.60 | 2.69 | 2.64 | 2.63 | 2.61 | 2.63 | 0.04 | 1.3 |
| 11/14/94 | 2:45 PM | 2.66 | 2.58 | 2.63 | 2.62 | 2.58 | 2.61 | 0.03 | 1.3 |

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg - Batch # 4320A**

Compression - Thickness (mm) - Front

| Date | Time | 1 | 2 | 3 | 4 | 5 | Average | St Dev. | RSD |
|----------|----------|------|------|------|------|------|---------|---------|-----|
| 11/14/94 | 5:15 PM | 2.62 | 2.65 | 2.66 | 2.68 | 2.65 | 2.65 | 0.02 | 0.8 |
| 11/14/94 | 5:45 PM | 2.64 | 2.60 | 2.64 | 2.61 | 2.64 | 2.63 | 0.02 | 0.7 |
| 11/14/94 | 6:15 PM | 2.67 | 2.61 | 2.61 | 2.66 | 2.63 | 2.64 | 0.03 | 1.1 |
| 11/14/94 | 6:45 PM | 2.66 | 2.59 | 2.62 | 2.59 | 2.60 | 2.61 | 0.03 | 1.1 |
| 11/14/94 | 7:15 PM | 2.62 | 2.61 | 2.58 | 2.61 | 2.64 | 2.61 | 0.02 | 0.8 |
| 11/14/94 | 7:45 PM | 2.62 | 2.62 | 2.64 | 2.65 | 2.62 | 2.63 | 0.01 | 0.5 |
| 11/14/94 | 8:15 PM | 2.63 | 2.66 | 2.64 | 2.66 | 2.69 | 2.66 | 0.02 | 0.9 |
| 11/14/94 | 8:45 PM | 2.64 | 2.68 | 2.69 | 2.63 | 2.63 | 2.65 | 0.03 | 1.1 |
| 11/15/94 | 8:00 AM | 2.66 | 2.68 | 2.67 | 2.68 | 2.65 | 2.67 | 0.01 | 0.5 |
| 11/15/94 | 8:30 AM | 2.65 | 2.65 | 2.61 | 2.64 | 2.67 | 2.64 | 0.02 | 0.8 |
| 11/15/94 | 9:00 AM | 2.64 | 2.60 | 2.61 | 2.63 | 2.64 | 2.62 | 0.02 | 0.7 |
| 11/15/94 | 9:30 AM | 2.65 | 2.65 | 2.63 | 2.67 | 2.60 | 2.64 | 0.03 | 1.0 |
| 11/15/94 | 10:00 AM | 2.58 | 2.58 | 2.59 | 2.61 | 2.60 | 2.59 | 0.01 | 0.5 |
| 11/15/94 | 10:30 AM | 2.64 | 2.64 | 2.62 | 2.64 | 2.63 | 2.63 | 0.01 | 0.3 |
| 11/15/94 | 11:35 AM | 2.62 | 2.62 | 2.65 | 2.64 | 2.68 | 2.64 | 0.02 | 0.9 |
| 11/15/94 | 12:05 PM | 2.62 | 2.62 | 2.63 | 2.60 | 2.60 | 2.61 | 0.01 | 0.5 |
| 11/15/94 | 12:35 PM | 2.63 | 2.62 | 2.62 | 2.62 | 2.66 | 2.63 | 0.02 | 0.7 |
| 11/15/94 | 1:05 PM | 2.61 | 2.61 | 2.62 | 2.64 | 2.64 | 2.62 | 0.02 | 0.6 |
| 11/15/94 | 1:35 PM | 2.63 | 2.64 | 2.65 | 2.64 | 2.61 | 2.63 | 0.02 | 0.6 |
| 11/15/94 | 4:30 PM | 2.64 | 2.67 | 2.65 | 2.63 | 2.64 | 2.65 | 0.02 | 0.6 |
| 11/15/94 | 5:00 PM | 2.64 | 2.66 | 2.63 | 2.66 | 2.64 | 2.65 | 0.01 | 0.5 |
| 11/15/94 | 5:30 PM | 2.62 | 2.62 | 2.63 | 2.64 | 2.62 | 2.63 | 0.01 | 0.3 |
| 11/15/94 | 6:10 PM | 2.60 | 2.63 | 2.62 | 2.63 | 2.66 | 2.63 | 0.02 | 0.8 |
| 11/15/94 | 6:40 PM | 2.61 | 2.60 | 2.63 | 2.64 | 2.63 | 2.62 | 0.02 | 0.6 |
| 11/15/94 | 7:10 PM | 2.63 | 2.60 | 2.60 | 2.63 | 2.59 | 2.61 | 0.02 | 0.7 |
| 11/15/94 | 7:40 PM | 2.65 | 2.63 | 2.61 | 2.65 | 2.65 | 2.64 | 0.02 | 0.7 |
| 11/15/94 | 8:10 PM | 2.59 | 2.62 | 2.61 | 2.60 | 2.59 | 2.60 | 0.01 | 0.5 |
| 11/15/94 | 8:40 PM | 2.62 | 2.63 | 2.56 | 2.62 | 2.60 | 2.61 | 0.03 | 1.1 |
| 11/15/94 | 9:10 AM | 2.62 | 2.64 | 2.59 | 2.61 | 2.63 | 2.62 | 0.02 | 0.7 |

Compression - Thickness (mm) - Rear

| Date | Time | 1 | 2 | 3 | 4 | 5 | Average | St Dev. | RSD |
|----------|----------|------|------|------|------|------|---------|---------|-----|
| 11/14/94 | 5:15 PM | 2.61 | 2.62 | 2.67 | 2.58 | 2.58 | 2.61 | 0.04 | 1.4 |
| 11/14/94 | 5:45 PM | 2.64 | 2.61 | 2.63 | 2.63 | 2.61 | 2.62 | 0.01 | 0.5 |
| 11/14/94 | 6:15 PM | 2.56 | 2.65 | 2.61 | 2.64 | 2.55 | 2.60 | 0.05 | 1.7 |
| 11/14/94 | 6:45 PM | 2.54 | 2.57 | 2.56 | 2.59 | 2.59 | 2.57 | 0.02 | 0.8 |
| 11/14/94 | 7:15 PM | 2.60 | 2.59 | 2.55 | 2.58 | 2.60 | 2.58 | 0.02 | 0.8 |
| 11/14/94 | 7:45 PM | 2.66 | 2.63 | 2.65 | 2.61 | 2.60 | 2.63 | 0.03 | 1.0 |
| 11/14/94 | 8:15 PM | 2.60 | 2.66 | 2.69 | 2.65 | 2.67 | 2.65 | 0.03 | 1.3 |
| 11/14/94 | 8:45 PM | 2.67 | 2.66 | 2.62 | 2.64 | 2.60 | 2.64 | 0.03 | 1.1 |
| 11/15/94 | 8:00 AM | 2.64 | 2.61 | 2.62 | 2.68 | 2.66 | 2.64 | 0.03 | 1.1 |
| 11/15/94 | 8:30 AM | 2.59 | 2.63 | 2.58 | 2.61 | 2.57 | 2.60 | 0.02 | 0.9 |
| 11/15/94 | 9:00 AM | 2.56 | 2.63 | 2.62 | 2.63 | 2.60 | 2.61 | 0.03 | 1.1 |
| 11/15/94 | 9:30 AM | 2.61 | 2.63 | 2.57 | 2.61 | 2.63 | 2.61 | 0.02 | 0.9 |
| 11/15/94 | 10:00 AM | 2.63 | 2.61 | 2.63 | 2.65 | 2.59 | 2.62 | 0.02 | 0.9 |
| 11/15/94 | 10:30 AM | 2.62 | 2.67 | 2.59 | 2.61 | 2.60 | 2.62 | 0.03 | 1.2 |
| 11/15/94 | 11:35 AM | 2.63 | 2.64 | 2.59 | 2.57 | 2.58 | 2.60 | 0.03 | 1.2 |
| 11/15/94 | 12:05 PM | 2.66 | 2.60 | 2.61 | 2.66 | 2.65 | 2.64 | 0.03 | 1.1 |
| 11/15/94 | 12:35 PM | 2.62 | 2.59 | 2.61 | 2.64 | 2.58 | 2.61 | 0.02 | 0.9 |
| 11/15/94 | 1:05 PM | 2.63 | 2.62 | 2.56 | 2.59 | 2.61 | 2.60 | 0.03 | 1.1 |
| 11/15/94 | 1:35 PM | 2.58 | 2.62 | 2.62 | 2.65 | 2.65 | 2.62 | 0.03 | 1.1 |
| 11/15/94 | 4:30 PM | 2.59 | 2.64 | 2.65 | 2.61 | 2.62 | 2.62 | 0.02 | 0.9 |
| 11/15/94 | 5:00 PM | 2.63 | 2.63 | 2.65 | 2.62 | 2.64 | 2.63 | 0.01 | 0.4 |
| 11/15/94 | 5:30 PM | 2.57 | 2.60 | 2.64 | 2.60 | 2.61 | 2.60 | 0.03 | 1.0 |
| 11/15/94 | 6:10 PM | 2.63 | 2.61 | 2.57 | 2.59 | 2.59 | 2.60 | 0.02 | 0.9 |
| 11/15/94 | 6:40 PM | 2.61 | 2.60 | 2.62 | 2.59 | 2.61 | 2.61 | 0.01 | 0.4 |
| 11/15/94 | 7:10 PM | 2.62 | 2.55 | 2.55 | 2.60 | 2.57 | 2.58 | 0.03 | 1.2 |
| 11/15/94 | 7:40 PM | 2.65 | 2.62 | 2.64 | 2.62 | 2.61 | 2.63 | 0.02 | 0.6 |
| 11/15/94 | 8:10 PM | 2.60 | 2.61 | 2.58 | 2.57 | 2.62 | 2.60 | 0.02 | 0.8 |
| 11/15/94 | 8:40 PM | 2.55 | 2.59 | 2.61 | 2.61 | 2.60 | 2.59 | 0.02 | 1.0 |
| 11/15/94 | 9:10 AM | 2.60 | 2.56 | 2.55 | 2.58 | 2.55 | 2.57 | 0.02 | 0.8 |

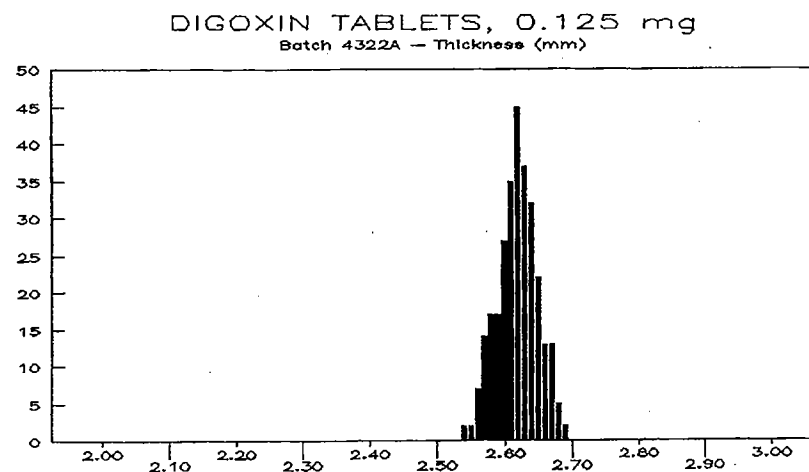
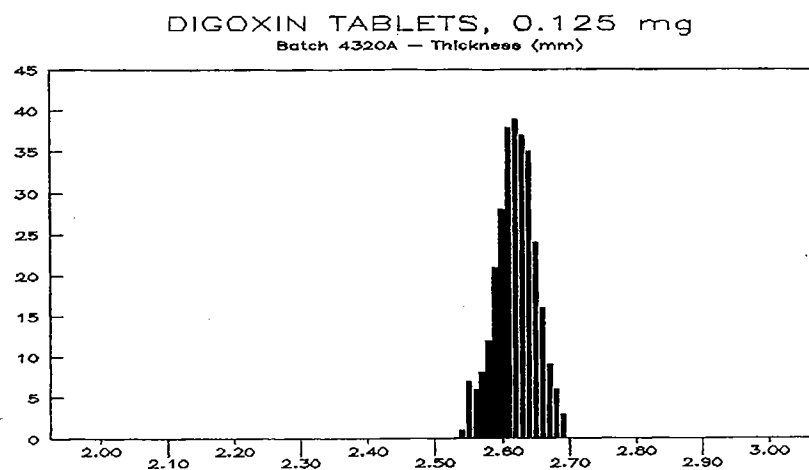
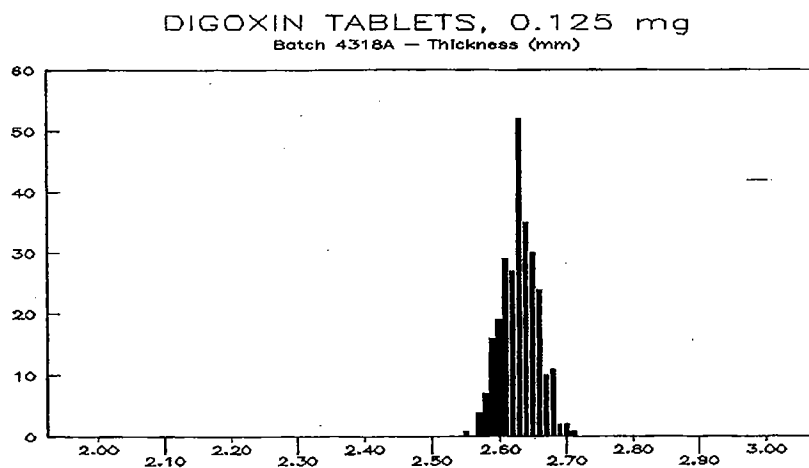
AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg - Batch # 4322A**

Compression - Thickness (mm) - Front

| Date | Time | 1 | 2 | 3 | 4 | 5 | Average | St Dev. | RSD |
|----------|----------|------|------|------|------|------|---------|---------|-----|
| 11/16/94 | 12:15 PM | 2.64 | 2.64 | 2.69 | 2.64 | 2.66 | 2.65 | 0.02 | 0.8 |
| 11/16/94 | 12:45 PM | 2.64 | 2.63 | 2.66 | 2.63 | 2.67 | 2.65 | 0.02 | 0.7 |
| 11/16/94 | 1:15 PM | 2.67 | 2.64 | 2.62 | 2.65 | 2.65 | 2.65 | 0.02 | 0.7 |
| 11/16/94 | 1:45 PM | 2.61 | 2.62 | 2.63 | 2.67 | 2.62 | 2.63 | 0.02 | 0.9 |
| 11/16/94 | 2:30 PM | 2.64 | 2.64 | 2.62 | 2.58 | 2.63 | 2.62 | 0.02 | 0.9 |
| 11/16/94 | 3:00 PM | 2.63 | 2.60 | 2.62 | 2.63 | 2.62 | 2.62 | 0.01 | 0.5 |
| 11/16/94 | 3:35 PM | 2.61 | 2.64 | 2.64 | 2.63 | 2.64 | 2.63 | 0.01 | 0.5 |
| 11/16/94 | 4:05 PM | 2.65 | 2.63 | 2.67 | 2.65 | 2.61 | 2.64 | 0.02 | 0.9 |
| 11/16/94 | 4:35 PM | 2.65 | 2.63 | 2.64 | 2.62 | 2.65 | 2.64 | 0.01 | 0.5 |
| 11/16/94 | 5:05 PM | 2.63 | 2.60 | 2.62 | 2.62 | 2.61 | 2.62 | 0.01 | 0.4 |
| 11/17/94 | 8:00 AM | 2.64 | 2.67 | 2.66 | 2.64 | 2.69 | 2.66 | 0.02 | 0.8 |
| 11/17/94 | 8:30 AM | 2.67 | 2.67 | 2.63 | 2.67 | 2.65 | 2.66 | 0.02 | 0.7 |
| 11/17/94 | 9:00 AM | 2.63 | 2.64 | 2.62 | 2.63 | 2.60 | 2.62 | 0.02 | 0.6 |
| 11/17/94 | 9:30 AM | 2.62 | 2.61 | 2.63 | 2.61 | 2.62 | 2.62 | 0.01 | 0.3 |
| 11/17/94 | 10:00 AM | 2.57 | 2.59 | 2.63 | 2.63 | 2.61 | 2.61 | 0.03 | 1.0 |
| 11/17/94 | 10:30 AM | 2.62 | 2.60 | 2.62 | 2.61 | 2.61 | 2.61 | 0.01 | 0.3 |
| 11/17/94 | 11:35 AM | 2.64 | 2.59 | 2.64 | 2.61 | 2.64 | 2.62 | 0.02 | 0.9 |
| 11/17/94 | 12:05 PM | 2.61 | 2.59 | 2.62 | 2.59 | 2.58 | 2.60 | 0.02 | 0.6 |
| 11/17/94 | 12:35 PM | 2.62 | 2.61 | 2.65 | 2.61 | 2.63 | 2.62 | 0.02 | 0.6 |
| 11/17/94 | 1:45 PM | 2.63 | 2.63 | 2.68 | 2.64 | 2.57 | 2.63 | 0.04 | 1.5 |
| 11/17/94 | 2:35 PM | 2.66 | 2.60 | 2.62 | 2.62 | 2.61 | 2.62 | 0.02 | 0.9 |
| 11/17/94 | 3:05 PM | 2.65 | 2.60 | 2.62 | 2.59 | 2.60 | 2.61 | 0.02 | 0.9 |
| 11/17/94 | 3:30 PM | 2.60 | 2.62 | 2.62 | 2.62 | 2.61 | 2.61 | 0.01 | 0.3 |
| 11/17/94 | 4:00 PM | 2.61 | 2.62 | 2.60 | 2.60 | 2.59 | 2.60 | 0.01 | 0.4 |
| 11/17/94 | 4:30 PM | 2.64 | 2.65 | 2.61 | 2.59 | 2.66 | 2.63 | 0.03 | 1.1 |
| 11/17/94 | 5:05 PM | 2.60 | 2.62 | 2.63 | 2.61 | 2.61 | 2.61 | 0.01 | 0.4 |
| 11/17/94 | 5:35 PM | 2.62 | 2.63 | 2.64 | 2.59 | 2.61 | 2.62 | 0.02 | 0.7 |
| 11/17/94 | 6:25 PM | 2.63 | 2.66 | 2.60 | 2.66 | 2.61 | 2.63 | 0.03 | 1.1 |
| 11/17/94 | 6:55 PM | 2.64 | 2.66 | 2.62 | 2.62 | 2.67 | 2.64 | 0.02 | 0.9 |

Compression - Thickness (mm) - Rear

| Date | Time | 1 | 2 | 3 | 4 | 5 | Average | St Dev. | RSD |
|----------|----------|------|------|------|------|------|---------|---------|-----|
| 11/16/94 | 12:15 PM | 2.65 | 2.67 | 2.63 | 2.66 | 2.63 | 2.65 | 0.02 | 0.7 |
| 11/16/94 | 12:45 PM | 2.65 | 2.63 | 2.63 | 2.60 | 2.60 | 2.62 | 0.02 | 0.8 |
| 11/16/94 | 1:15 PM | 2.58 | 2.65 | 2.66 | 2.59 | 2.61 | 2.62 | 0.04 | 1.4 |
| 11/16/94 | 1:45 PM | 2.65 | 2.60 | 2.65 | 2.66 | 2.64 | 2.64 | 0.02 | 0.9 |
| 11/16/94 | 2:30 PM | 2.61 | 2.63 | 2.63 | 2.58 | 2.55 | 2.60 | 0.03 | 1.3 |
| 11/16/94 | 3:00 PM | 2.63 | 2.58 | 2.65 | 2.61 | 2.62 | 2.62 | 0.03 | 1.0 |
| 11/16/94 | 3:35 PM | 2.65 | 2.59 | 2.58 | 2.60 | 2.61 | 2.61 | 0.03 | 1.0 |
| 11/16/94 | 4:05 PM | 2.60 | 2.63 | 2.58 | 2.62 | 2.67 | 2.62 | 0.03 | 1.3 |
| 11/16/94 | 4:35 PM | 2.60 | 2.56 | 2.58 | 2.63 | 2.61 | 2.60 | 0.03 | 1.0 |
| 11/16/94 | 5:05 PM | 2.63 | 2.60 | 2.62 | 2.58 | 2.65 | 2.62 | 0.03 | 1.0 |
| 11/17/94 | 8:00 AM | 2.68 | 2.67 | 2.65 | 2.66 | 2.62 | 2.66 | 0.02 | 0.9 |
| 11/17/94 | 8:30 AM | 2.61 | 2.64 | 2.68 | 2.68 | 2.67 | 2.66 | 0.03 | 1.1 |
| 11/17/94 | 9:00 AM | 2.62 | 2.57 | 2.57 | 2.63 | 2.60 | 2.60 | 0.03 | 1.1 |
| 11/17/94 | 9:30 AM | 2.63 | 2.61 | 2.62 | 2.64 | 2.57 | 2.61 | 0.03 | 1.0 |
| 11/17/94 | 10:00 AM | 2.59 | 2.59 | 2.64 | 2.64 | 2.57 | 2.61 | 0.03 | 1.2 |
| 11/17/94 | 10:30 AM | 2.57 | 2.62 | 2.61 | 2.57 | 2.61 | 2.60 | 0.02 | 0.9 |
| 11/17/94 | 11:35 AM | 2.58 | 2.62 | 2.62 | 2.56 | 2.57 | 2.59 | 0.03 | 1.1 |
| 11/17/94 | 12:05 PM | 2.57 | 2.56 | 2.61 | 2.56 | 2.63 | 2.59 | 0.03 | 1.2 |
| 11/17/94 | 12:35 PM | 2.62 | 2.54 | 2.58 | 2.54 | 2.62 | 2.58 | 0.04 | 1.6 |
| 11/17/94 | 1:45 PM | 2.65 | 2.60 | 2.64 | 2.64 | 2.61 | 2.63 | 0.02 | 0.8 |
| 11/17/94 | 2:35 PM | 2.60 | 2.65 | 2.58 | 2.60 | 2.65 | 2.62 | 0.03 | 1.2 |
| 11/17/94 | 3:05 PM | 2.58 | 2.62 | 2.59 | 2.61 | 2.56 | 2.59 | 0.02 | 0.9 |
| 11/17/94 | 3:30 PM | 2.62 | 2.64 | 2.60 | 2.59 | 2.56 | 2.60 | 0.03 | 1.2 |
| 11/17/94 | 4:00 PM | 2.62 | 2.58 | 2.56 | 2.58 | 2.64 | 2.60 | 0.03 | 1.3 |
| 11/17/94 | 4:30 PM | 2.58 | 2.64 | 2.63 | 2.61 | 2.63 | 2.62 | 0.02 | 0.9 |
| 11/17/94 | 5:05 PM | 2.61 | 2.57 | 2.59 | 2.66 | 2.62 | 2.61 | 0.03 | 1.3 |
| 11/17/94 | 5:35 PM | 2.60 | 2.57 | 2.57 | 2.59 | 2.55 | 2.58 | 0.02 | 0.8 |
| 11/17/94 | 6:25 PM | 2.62 | 2.60 | 2.58 | 2.61 | 2.59 | 2.60 | 0.02 | 0.6 |
| 11/17/94 | 6:55 PM | 2.68 | 2.60 | 2.62 | 2.64 | 2.57 | 2.62 | 0.04 | 1.6 |



AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Compression - Friability (%)

| Batch # | 4318A | 4318A | 4320A | 4320A | 4320A | 4322A | 4322A |
|-------------|-------|-------|-------|-------|-------|-------|-------|
| Side | Front | Rear | Front | Rear | Front | Front | Rear |
| 1st Third | 0.1 | 0.1 | 0.04 | 0.1 | 0.1 | 0.1 | 0.1 |
| 2nd Third | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Final Third | 0.1 | 0.03 | 0.1 | 0.04 | 0.04 | 0.03 | 0.03 |
| Average | 0.10 | 0.08 | 0.08 | 0.08 | 0.08 | 0.08 | 0.08 |
| St Dev. | 0.00 | 0.04 | 0.03 | 0.03 | 0.03 | 0.03 | 0.04 |
| RSD | 0.0 | 52.7 | 43.3 | 43.3 | 43.3 | 43.3 | 52.7 |

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Compression - Disintegration (min.)

| Batch # | 4318A | 4318A | 4320A | 4320A | 4320A | 4322A | 4322A |
|-------------|-------|-------|-------|-------|-------|-------|-------|
| Side | Front | Rear | Front | Rear | Front | Rear | Front |
| 1st Third | 3 | 3 | 4 | 3 | 3 | 3 | 3 |
| 2nd Third | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Final Third | 3 | 4 | 3 | 4 | 4 | 4 | 4 |
| Average | 3.0 | 3.3 | 3.3 | 3.3 | 3.3 | 3.3 | 3.3 |
| St Dev. | 0.0 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 |
| RSD | 0.0 | 17.3 | 17.3 | 17.3 | 17.3 | 17.3 | 17.3 |

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION*****DIGOXIN TABLETS, 0.125 mg***

Compression - Content Uniformity (%)

| Batch # | 4318A | 4318A | 4320A | 4320A | 4322A | 4322A |
|---------|-------|-------|-------|-------|-------|-------|
| Side | Front | Rear | Front | Rear | Front | Rear |
| 1 | 100.6 | 99.5 | 102.8 | 101.4 | 101.7 | 102.9 |
| 2 | 101.1 | 102.2 | 96.2 | 100.5 | 104.6 | 97.9 |
| 3 | 103.5 | 102.9 | 101.2 | 101.7 | 101.0 | 99.1 |
| 4 | 100.9 | 101.5 | 101.4 | 99.8 | 102.5 | 99.3 |
| 5 | 101.9 | 101.1 | 100.6 | 99.0 | 103.1 | 99.8 |
| 6 | 101.6 | 102.4 | 99.6 | 99.6 | 101.6 | 99.1 |
| 7 | 100.1 | 98.9 | 99.3 | 100.8 | 102.3 | 99.9 |
| 8 | 101.4 | 101.8 | 99.9 | 100.9 | 99.6 | 100.5 |
| 9 | 101.9 | 102.6 | 100.0 | 102.0 | 100.1 | 102.0 |
| 10 | 101.4 | 102.4 | 99.3 | 97.3 | 104.2 | 101.4 |
| 11 | 102.3 | 101.1 | 98.0 | 101.2 | 102.9 | 100.7 |
| 12 | 99.8 | 101.6 | 98.7 | 99.4 | 103.4 | 100.2 |
| 13 | 101.4 | 98.9 | 100.8 | 97.4 | 102.1 | 101.5 |
| 14 | 102.2 | 102.0 | 101.6 | 98.6 | 100.9 | 99.4 |
| 15 | 101.8 | 102.0 | 101.0 | 100.7 | 102.6 | 100.6 |
| 16 | 101.2 | 103.6 | 99.1 | 100.6 | 101.1 | 99.3 |
| 17 | 101.5 | 101.2 | 98.0 | 100.3 | 103.3 | 102.1 |
| 18 | 99.9 | 101.4 | 100.1 | 100.1 | 104.8 | 102.1 |
| 19 | 103.5 | 102.4 | 100.2 | 99.7 | 103.5 | 99.3 |
| 20 | 102.4 | 100.7 | 93.8 | 100.6 | 103.9 | 101.4 |
| 21 | 100.8 | 101.0 | 102.0 | 100.7 | 102.7 | 98.9 |
| 22 | 100.9 | 100.8 | 103.1 | 100.3 | 103.9 | 99.8 |
| 23 | 98.7 | 99.7 | 102.3 | 99.8 | 102.6 | 99.2 |
| 24 | 100.9 | 100.9 | 103.8 | 100.5 | 103.2 | 100.5 |
| 25 | 102.1 | 100.6 | 101.2 | 102.3 | 102.1 | 99.6 |
| 26 | 101.7 | 99.9 | 101.0 | 99.9 | 100.1 | 101.0 |
| 27 | 100.4 | 101.0 | 102.3 | 101.0 | 101.3 | 102.0 |
| 28 | 101.0 | 101.2 | 102.9 | 100.6 | 100.0 | 98.9 |
| 29 | 101.1 | 102.2 | 99.0 | 101.2 | 98.6 | 100.7 |
| 30 | 103.2 | 100.1 | 103.6 | 101.5 | 102.0 | 101.6 |
| Average | 101.4 | 101.3 | 100.4 | 100.3 | 102.2 | 100.4 |
| St Dev. | 1.1 | 1.2 | 2.2 | 1.2 | 1.5 | 1.2 |
| RSD | 1.0 | 1.1 | 2.2 | 1.2 | 1.5 | 1.2 |

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

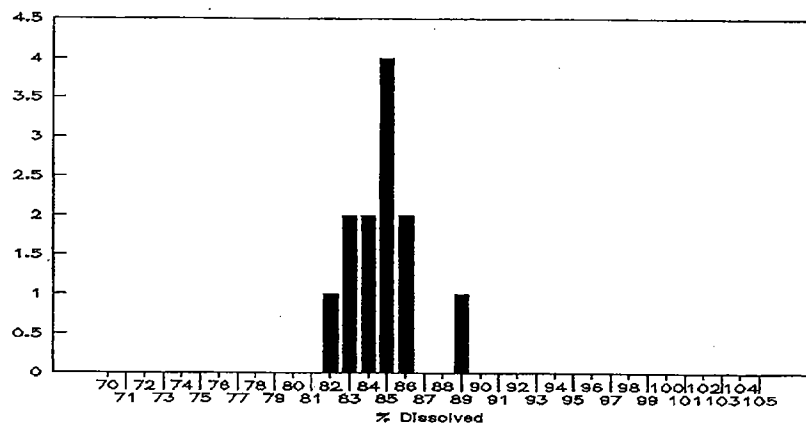
Compression - Dissolution (%) - 15 min.

| Batch # | 4318A | 4318A | 4318A | 4320A | 4320A | 4320A | 4320A | 4322A | 4322A | 4322A |
|---------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Sample | 1st | Thrid | Final | 1st | Thrid | 2nd | Final | 1st | Thrid | Final |
| 1 | 84.7 | 81.8 | 77.5 | 83.1 | 82.7 | 85.8 | 87.5 | 81.6 | 81.7 | 79.3 |
| 2 | 88.1 | 81.2 | 82.3 | 82.7 | 84.3 | 87.0 | 87.0 | 81.7 | 81.2 | 84.2 |
| 3 | 84.5 | 81.3 | 85.0 | 82.2 | 84.7 | 82.3 | 85.5 | 80.1 | 79.3 | 81.6 |
| 4 | 85.5 | 83.3 | 80.9 | 81.5 | 84.3 | 85.5 | 82.7 | 82.7 | 82.5 | 82.0 |
| 5 | 85.6 | 81.6 | 77.7 | 81.6 | 84.4 | 87.3 | 84.8 | 85.4 | 80.7 | 80.1 |
| 6 | 82.3 | 83.4 | 84.0 | 84.1 | 87.3 | 86.4 | 81.4 | 81.3 | 81.0 | 80.5 |
| 7 | 83.3 | 83.9 | 83.6 | 86.1 | 86.4 | 87.1 | 87.9 | 83.3 | 83.0 | 80.5 |
| 8 | 81.8 | 79.7 | 83.3 | 84.5 | 87.1 | 88.0 | 84.6 | 80.2 | 78.4 | 83.2 |
| 9 | 84.0 | 80.1 | 81.3 | 87.2 | 88.0 | 87.0 | 83.4 | 85.8 | 75.0 | 84.1 |
| 10 | 84.7 | 84.2 | 85.9 | 84.9 | 87.0 | 86.6 | 80.9 | 85.0 | 77.9 | 85.6 |
| 11 | 83.0 | 83.6 | 83.7 | 87.7 | 86.6 | 86.6 | 84.1 | 83.5 | 78.9 | 80.4 |
| 12 | 84.1 | 82.6 | 84.0 | 88.0 | 86.0 | 86.0 | 84.3 | 82.7 | 79.4 | 82.1 |
| Average | 84.3 | 82.2 | 82.4 | 84.5 | 86.0 | 86.0 | 84.3 | 82.7 | 79.4 | 82.1 |
| St Dev. | 1.7 | 1.5 | 2.7 | 2.3 | 1.3 | 1.3 | 2.3 | 1.9 | 2.4 | 1.8 |
| RSD | 2.0 | 1.8 | 3.2 | 2.8 | 1.5 | 1.5 | 2.8 | 2.3 | 3.0 | 2.2 |

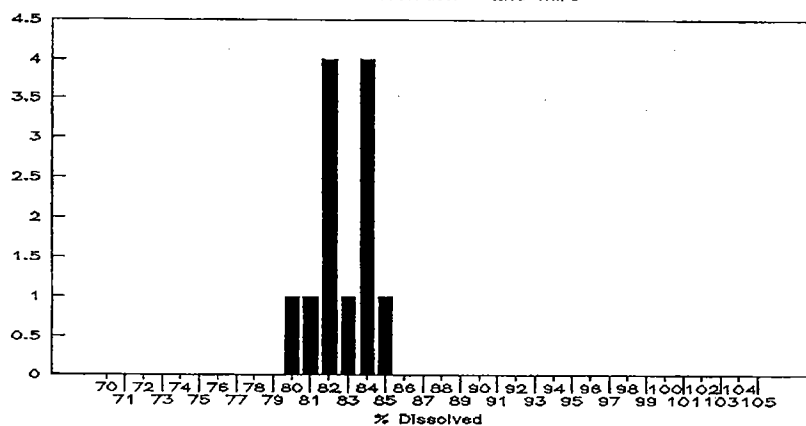
Compression - Dissolution (%) - 60 min.

| Batch # | 4318A | 4318A | 4318A | 4320A | 4320A | 4320A | 4320A | 4322A | 4322A | 4322A |
|---------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Sample | 1st | Thrid | Final | 1st | Thrid | 2nd | Final | 1st | Thrid | Final |
| 1 | 93.7 | 95.3 | 98.1 | 104.3 | 94.4 | 96.3 | 95.6 | 94.7 | 94.6 | 92.3 |
| 2 | 97.2 | 96.2 | 93.3 | 102.0 | 96.3 | 97.9 | 100.4 | 96.4 | 94.5 | 97.4 |
| 3 | 98.3 | 95.0 | 97.0 | 104.9 | 97.9 | 99.2 | 100.3 | 94.5 | 96.1 | 95.3 |
| 4 | 99.4 | 99.5 | 94.8 | 106.9 | 99.2 | 100.7 | 101.1 | 100.1 | 93.3 | 103.6 |
| 5 | 96.7 | 97.9 | 95.6 | 91.5 | 100.7 | 101.8 | 93.5 | 99.1 | 92.7 | 96.9 |
| 6 | 97.4 | 99.5 | 95.1 | 101.0 | 98.7 | 96.7 | 102.7 | 101.2 | 96.2 | 102.5 |
| 7 | 96.5 | 95.9 | 98.3 | 99.9 | 96.7 | 102.6 | 104.4 | 96.3 | 97.7 | 97.1 |
| 8 | 98.5 | 96.2 | 94.7 | 99.5 | 102.6 | 100.9 | 99.8 | 98.0 | 97.1 | 96.1 |
| 9 | 97.8 | 95.3 | 93.4 | 102.2 | 98.9 | 100.5 | 97.7 | 103.0 | 93.5 | 99.2 |
| 10 | 95.4 | 101.7 | 95.4 | 98.9 | 98.5 | 97.9 | 97.7 | 100.5 | 94.0 | 99.6 |
| 11 | 98.0 | 101.2 | 96.6 | 97.9 | 98.5 | 97.4 | 100.5 | 99.1 | 97.6 | 91.7 |
| 12 | 100.6 | 102.2 | 99.6 | 97.4 | 100.5 | 98.9 | 99.5 | 98.6 | 94.9 | 98.1 |
| Average | 97.5 | 98.0 | 96.1 | 100.5 | 98.9 | 98.9 | 99.5 | 98.6 | 94.9 | 98.1 |
| St Dev. | 1.8 | 2.7 | 2.1 | 4.1 | 2.3 | 2.3 | 3.0 | 2.8 | 2.0 | 3.1 |
| RSD | 1.9 | 2.8 | 2.2 | 4.0 | 2.3 | 2.3 | 3.1 | 2.8 | 2.1 | 3.2 |

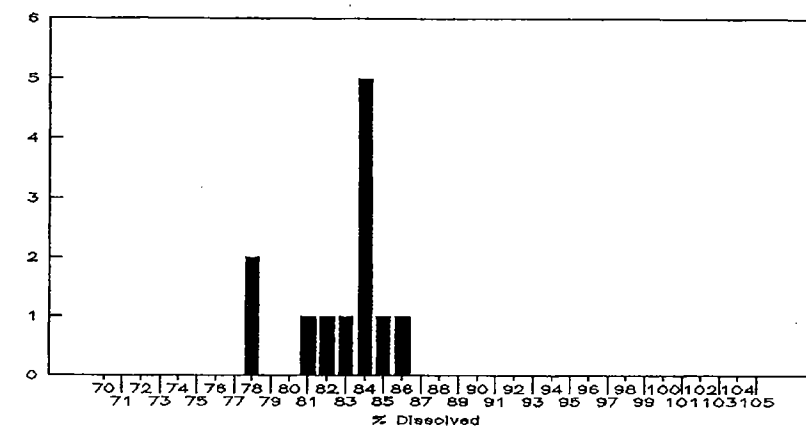
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
15 Min. Dissolution — 1st Third



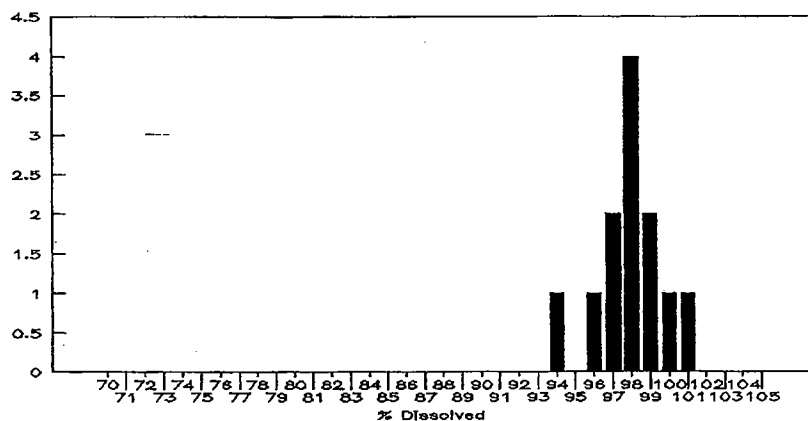
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
15 Min. Dissolution — 2nd Third



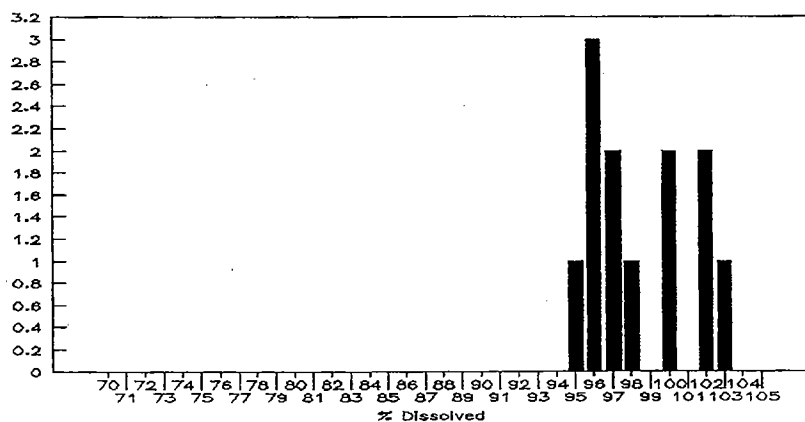
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
15 Min. Dissolution — Final Third



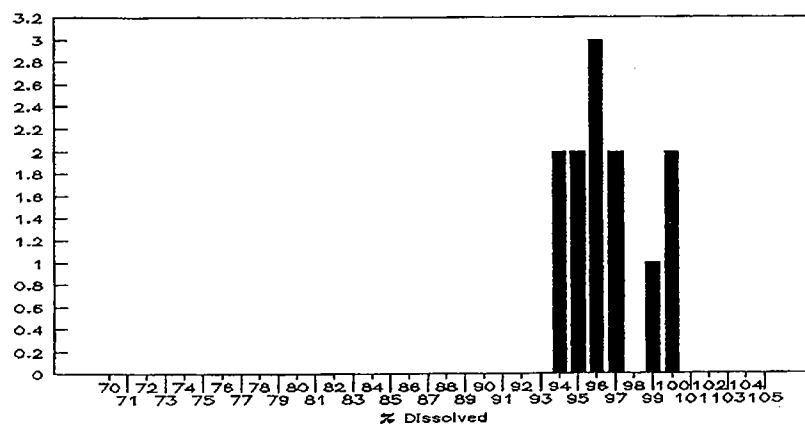
DIGOXIN TABLETS, 0.125 mg — Batch 4318A
60 Min. Dissolution — 1st Third



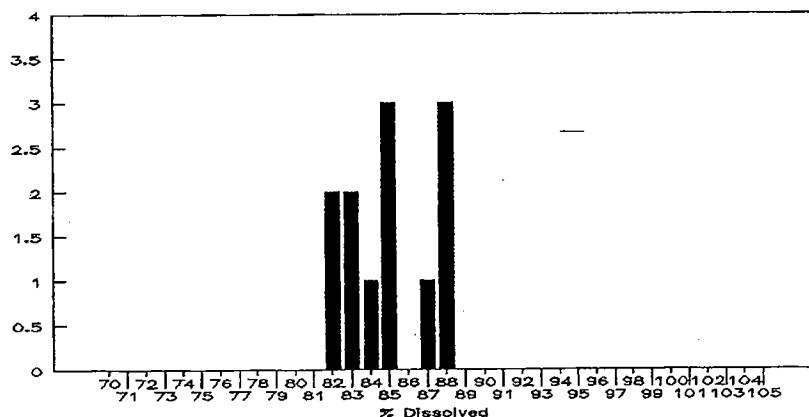
DIGOXIN TABLETS, 0.125 mg — Batch 4318A
60 Min. Dissolution — 2nd Third



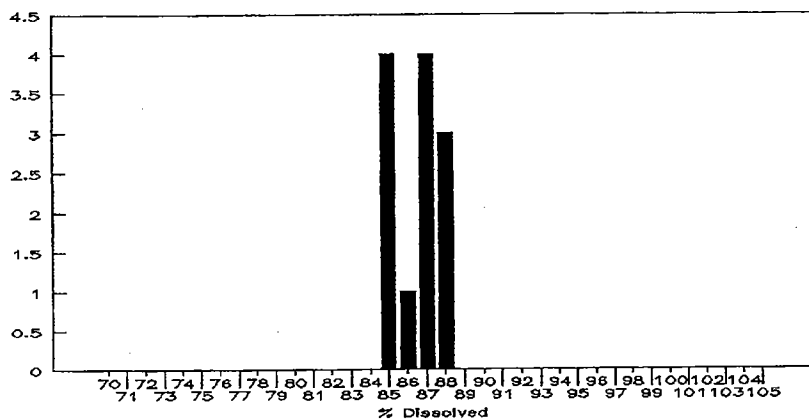
DIGOXIN TABLETS, 0.125 mg — Batch 4318A
60 Min. Dissolution — Final Third



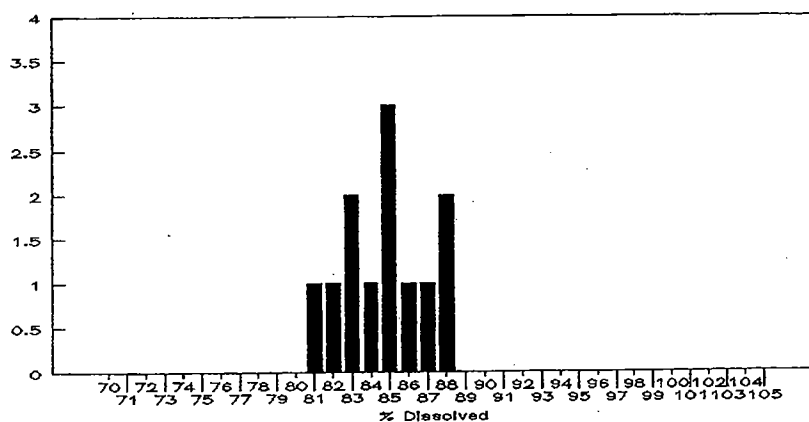
DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
15 Min. Dissolution — 1st Third



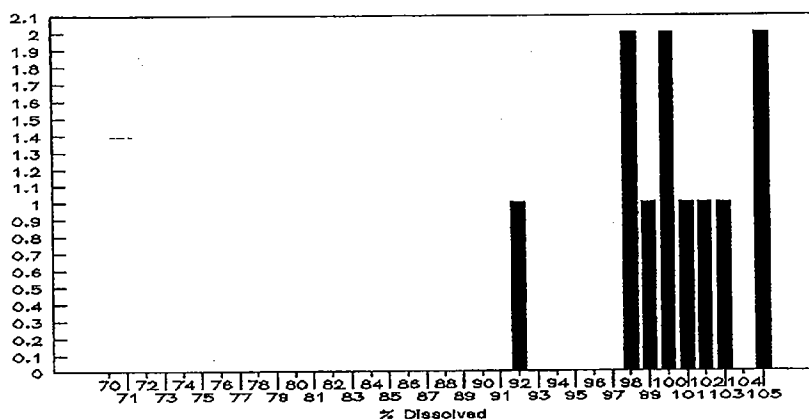
DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
15 Min. Dissolution — 2nd Third



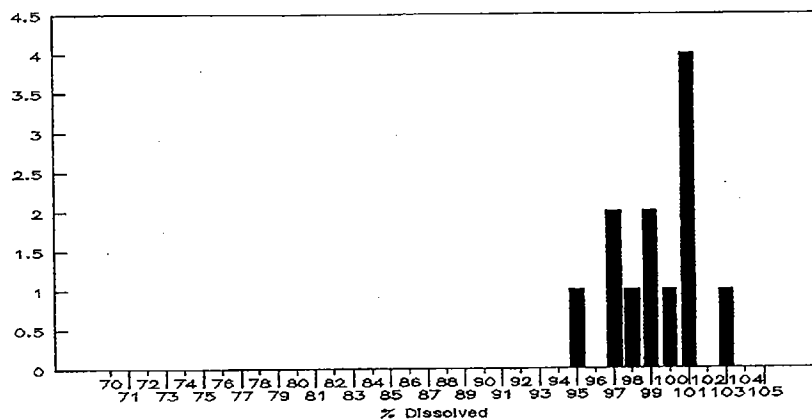
DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
15 Min. Dissolution — Final Third



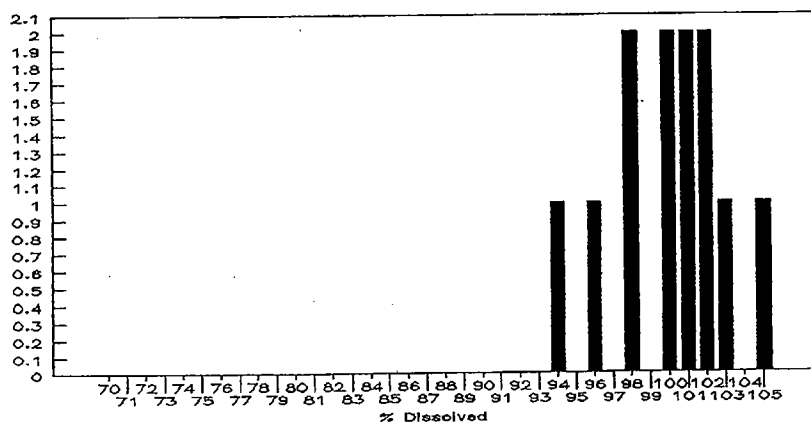
DIGOXIN TABLETS, 0.125 mg — Batch 4320A
60 Min. Dissolution — 1st Third



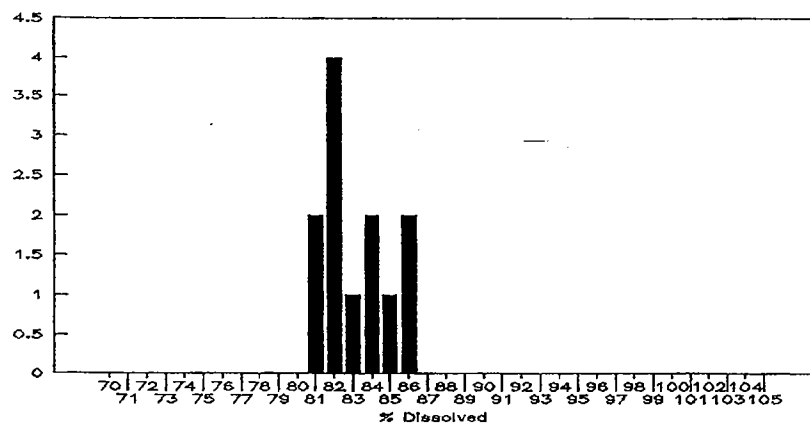
DIGOXIN TABLETS, 0.125 mg — Batch 4320A
60 Min. Dissolution — 2nd Third



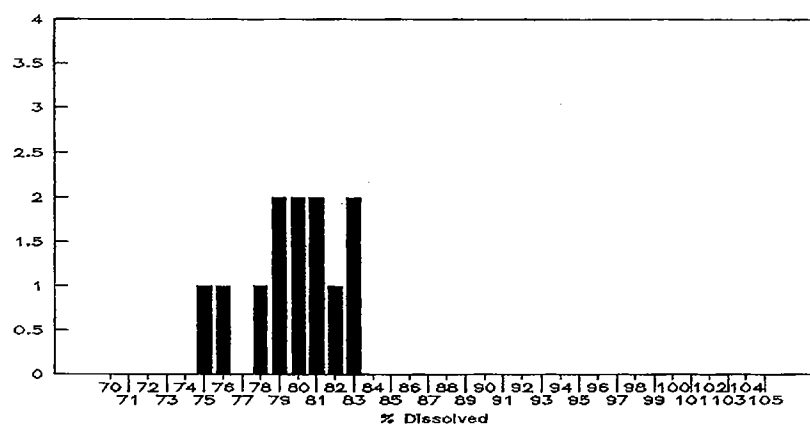
DIGOXIN TABLETS, 0.125 mg — Batch 4320A
60 Min. Dissolution — Final Third



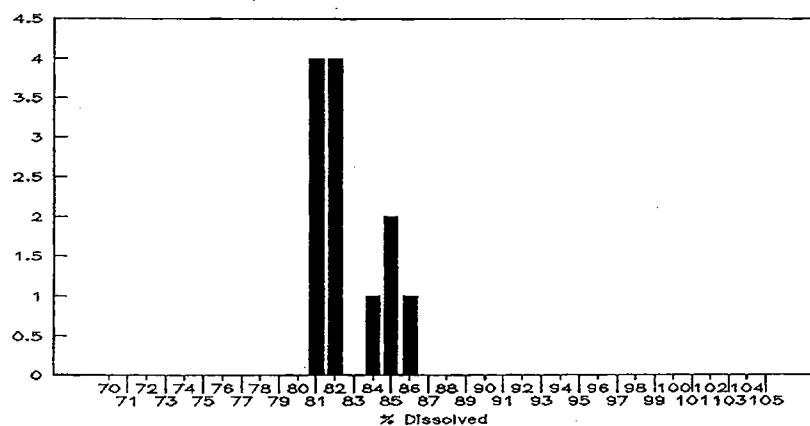
DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
15 Min. Dissolution — 1st Third



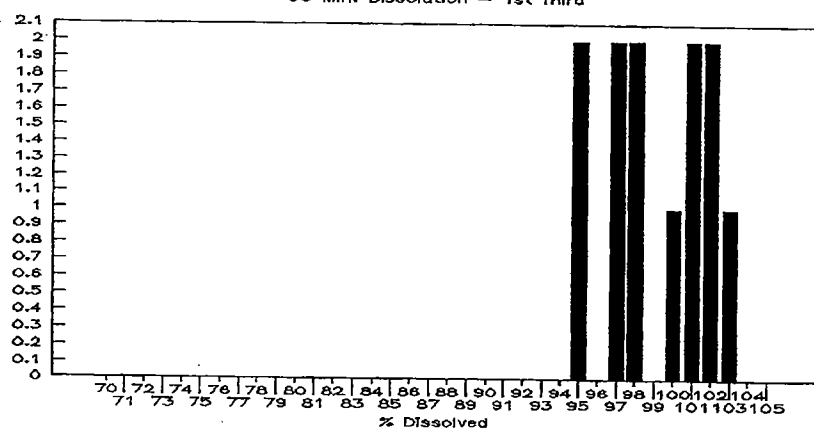
DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
15 Min. Dissolution — 2nd Third



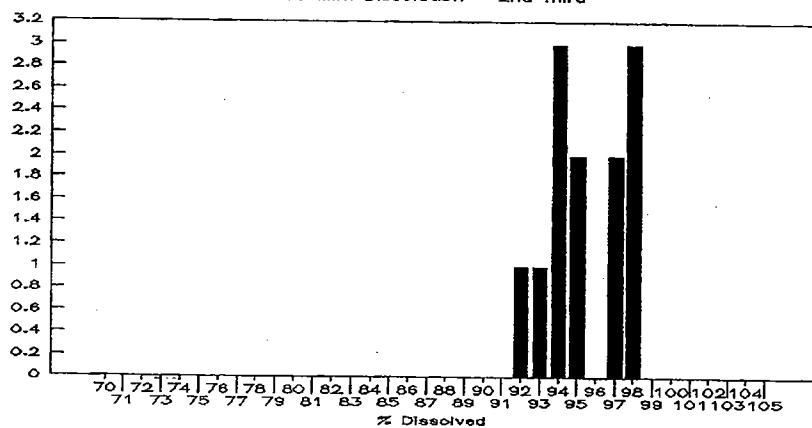
DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
15 Min. Dissolution — Final Third



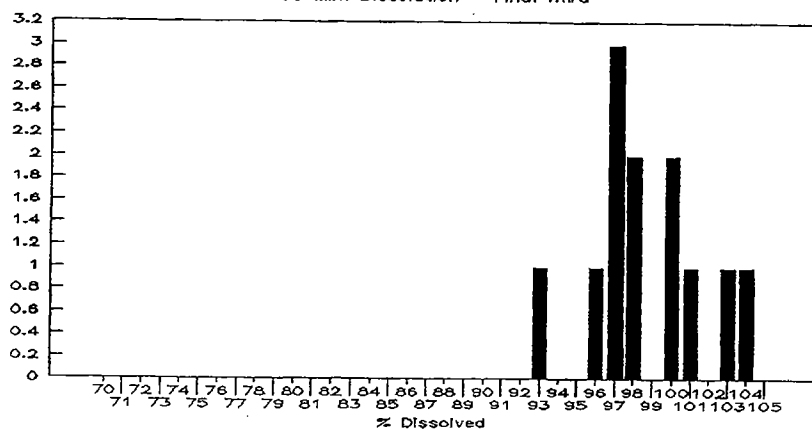
DIGOXIN TABLETS, 0.125 mg — Batch 4322A
60 Min. Dissolution — 1st Third



DIGOXIN TABLETS, 0.125 mg — Batch 4322A
60 Min. Dissolution — 2nd Third



DIGOXIN TABLETS, 0.125 mg — Batch 4322A
60 Min. Dissolution — Final Third

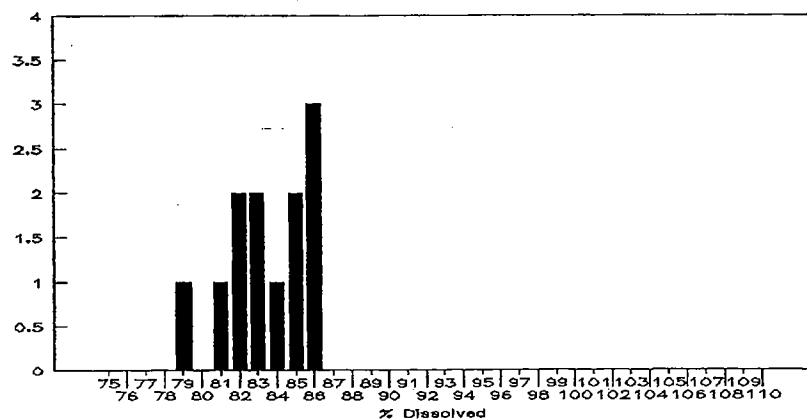


AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

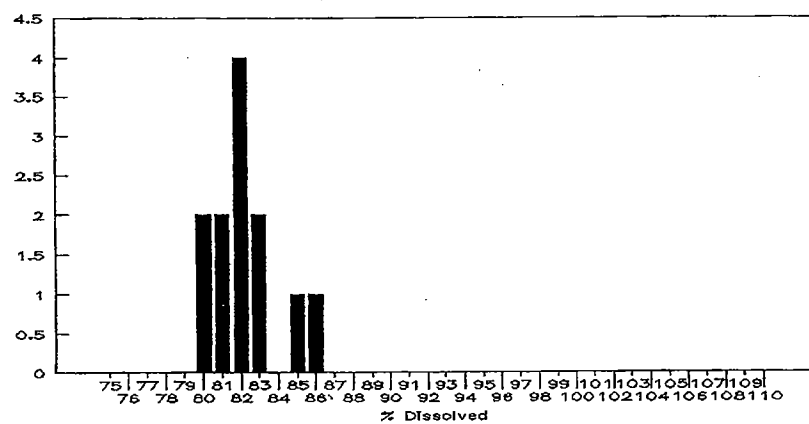
Compression - Composite Dissolution (%)

| Batch # | 4318A 15 min. | 4318A 60 min. | 4320A 15 min. | 4320A 60 min. | 4320A 15 min. | 4320A 60 min. | 4322A 15 min. | 4322A 60 min. |
|---------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| Time | | | | | | | | |
| 1 | 85.8 | 100.3 | 81.0 | 99.1 | 78.4 | 97.4 | | |
| 2 | 83.0 | 100.0 | 81.9 | 98.7 | 79.9 | 98.9 | | |
| 3 | 80.6 | 97.2 | 82.1 | 98.3 | 78.9 | 95.2 | | |
| 4 | 83.1 | 96.6 | 81.7 | 99.1 | 77.7 | 95.8 | | |
| 5 | 85.3 | 101.3 | 82.3 | 98.4 | 79.0 | 94.8 | | |
| 6 | 81.7 | 99.9 | 81.8 | 95.9 | 77.9 | 96.0 | | |
| 7 | 85.6 | 99.4 | 80.8 | 100.5 | 84.3 | 98.2 | | |
| 8 | 81.9 | 95.1 | 80.0 | 98.2 | 83.9 | 98.4 | | |
| 9 | 82.5 | 97.9 | 79.5 | 98.4 | 80.3 | 95.0 | | |
| 10 | 85.0 | 98.4 | 85.6 | 101.8 | 82.5 | 95.9 | | |
| 11 | 84.6 | 100.6 | 81.5 | 96.5 | 81.4 | 99.2 | | |
| 12 | 78.1 | 99.6 | 84.6 | 99.5 | 81.0 | 93.6 | | |
| Average | 83.1 | 98.9 | 81.9 | 98.7 | 80.4 | 96.5 | | |
| St Dev. | 2.3 | 1.8 | 1.7 | 1.6 | 2.2 | 1.8 | | |
| RSD | 2.8 | 1.9 | 2.1 | 1.6 | 2.8 | 1.9 | | |

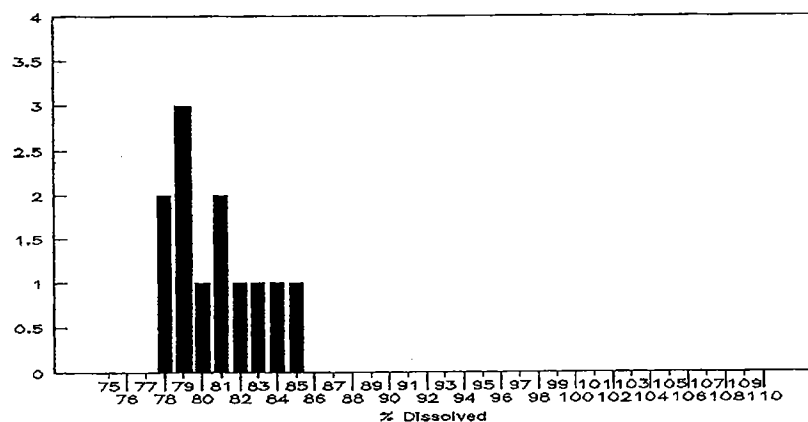
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
Composite — 15 Min. Dissolution



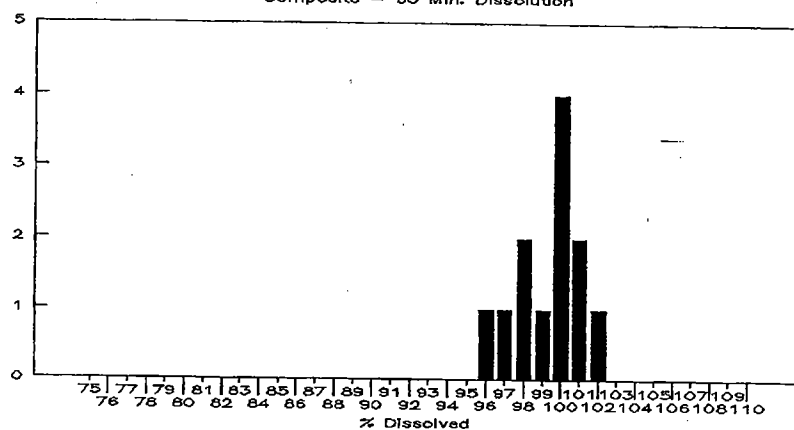
DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
Composite — 15 Min. Dissolution



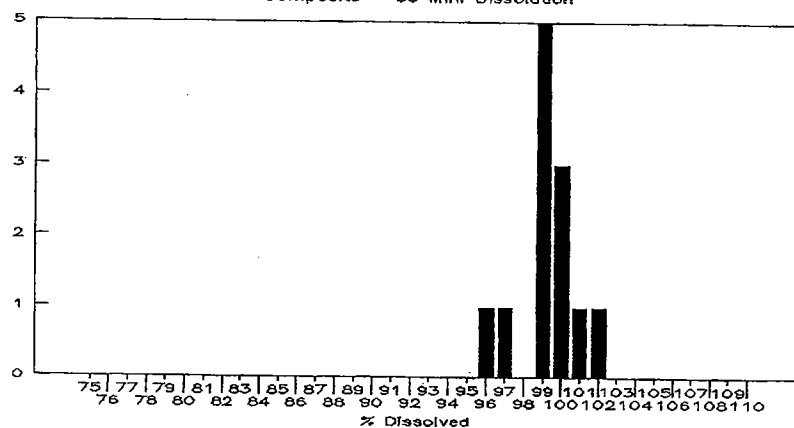
DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
Composite — 15 Min. Dissolution



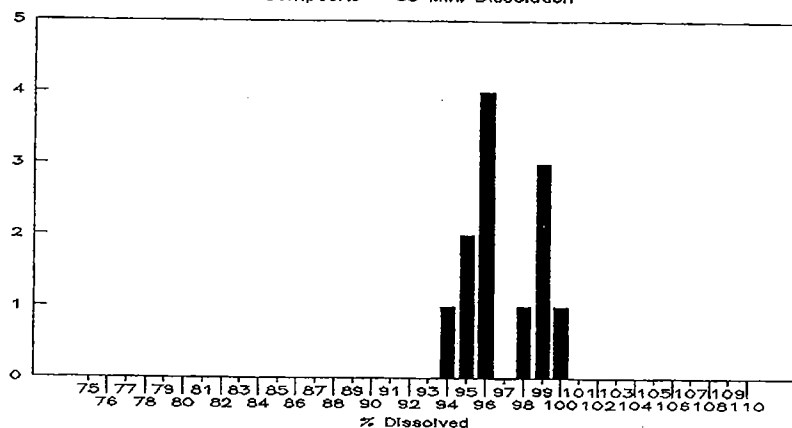
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
Composite — 60 Min. Dissolution



DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
Composite — 60 Min. Dissolution



DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
Composite — 60 Min. Dissolution



AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

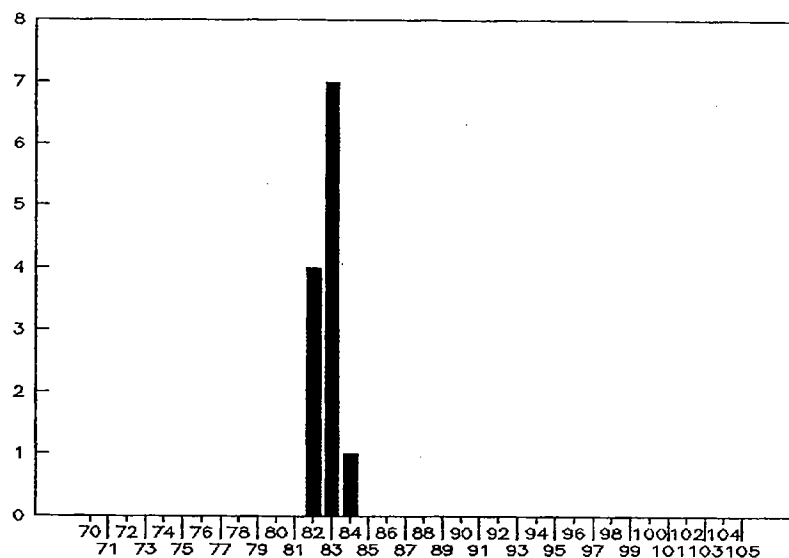
High/Low kp - Dissolution (%) - 15 min.

| Batch # | 4318A | 4318A | 4318A | 4318A | 4318A | 4318A | 4318A | 4318A | 4318A | 4320A | 4320A | 4320A | 4320A | 4320A | 4320A | 4322A | 4322A | 4322A | 4322A | 4322A | 4322A |
|---------|---------|---------|---------|--------|--------|--------|--------|--------|--------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Sample | High kp | High kp | High kp | Low kp | Low kp | Low kp | Low kp | Low kp | Low kp | High kp | High kp | High kp | High kp | High kp | High kp | High kp | High kp | High kp | High kp | High kp | High kp |
| Side | Front | Rear | Front | Front | Rear | Front | Front | Rear | Rear | Front | Rear | Front | Rear | Front | Rear | Front | Rear | Front | Rear | Front | Rear |
| 1 | 81.2 | 82.0 | 81.3 | 81.7 | 81.7 | 81.5 | 83.5 | 83.5 | 83.3 | 83.3 | 81.4 | 81.4 | 69.8 | 83.7 | 83.7 | 83.3 | 83.3 | 83.3 | 83.3 | 83.3 | 76.8 |
| 2 | 81.4 | 82.6 | 80.8 | 85.9 | 85.9 | 82.9 | 87.2 | 87.2 | 83.5 | 83.5 | 82.5 | 82.5 | 83.2 | 79.9 | 79.9 | 82.2 | 82.2 | 82.2 | 82.2 | 82.2 | 83.4 |
| 3 | 82.6 | 82.9 | 82.0 | 83.7 | 83.7 | 84.8 | 87.2 | 87.2 | 80.9 | 80.9 | 83.0 | 83.0 | 76.9 | 82.7 | 82.7 | 83.2 | 83.2 | 83.2 | 83.2 | 83.2 | 85.5 |
| 4 | 82.1 | 82.1 | 81.7 | 83.2 | 83.2 | 83.0 | 86.9 | 86.9 | 81.1 | 81.1 | 81.7 | 81.7 | 83.6 | 83.1 | 83.1 | 84.6 | 84.6 | 84.6 | 84.6 | 84.6 | 83.9 |
| 5 | 82.8 | 82.3 | 81.6 | 82.7 | 82.7 | 84.0 | 87.9 | 87.9 | 85.4 | 85.4 | 84.6 | 84.6 | 81.3 | 84.7 | 84.7 | 82.2 | 82.2 | 82.2 | 82.2 | 82.2 | 84.8 |
| 6 | 81.8 | 83.7 | 81.9 | 82.8 | 82.8 | 83.1 | 86.7 | 86.7 | 81.2 | 81.2 | 83.9 | 83.9 | 72.6 | 77.3 | 77.3 | 82.3 | 82.3 | 82.3 | 82.3 | 82.3 | 84.1 |
| Average | 82.0 | 82.6 | 81.6 | 83.3 | 83.3 | 83.2 | 86.6 | 86.6 | 82.6 | 82.6 | 82.9 | 82.9 | 77.9 | 81.9 | 81.9 | 83.0 | 83.0 | 83.0 | 83.0 | 83.0 | 83.1 |
| St Dev. | 0.6 | 0.6 | 0.4 | 1.4 | 1.4 | 1.1 | 1.6 | 1.6 | 1.8 | 1.8 | 1.2 | 1.2 | 5.8 | 2.8 | 2.8 | 0.9 | 0.9 | 0.9 | 0.9 | 0.9 | 3.2 |
| RSD | 0.8 | 0.8 | 0.5 | 1.7 | 1.7 | 1.3 | 1.8 | 1.8 | 2.2 | 2.2 | 1.5 | 1.5 | 7.4 | 3.4 | 3.4 | 1.1 | 1.1 | 1.1 | 1.1 | 1.1 | 3.8 |

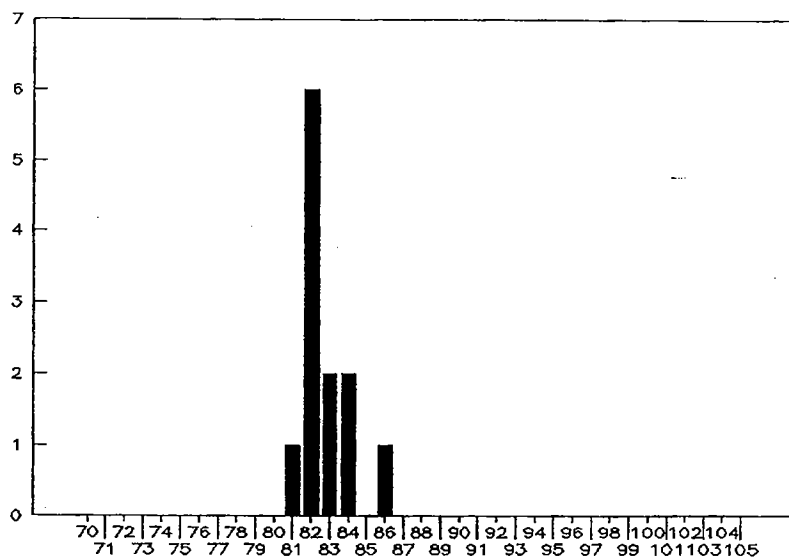
High/Low kp - Dissolution (%) - 60 min.

| Batch # | 4318A | 4318A | 4318A | 4318A | 4318A | 4318A | 4318A | 4318A | 4318A | 4320A | 4320A | 4320A | 4320A | 4320A | 4320A | 4322A | 4322A | 4322A | 4322A | 4322A | 4322A |
|---------|---------|---------|---------|--------|--------|--------|--------|--------|--------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Sample | High kp | High kp | High kp | Low kp | Low kp | Low kp | Low kp | Low kp | Low kp | High kp | High kp | High kp | High kp | High kp | High kp | High kp | High kp | High kp | High kp | High kp | High kp |
| Side | Front | Rear | Front | Front | Rear | Front | Front | Rear | Rear | Front | Rear | Front | Rear | Front | Rear | Front | Rear | Front | Rear | Front | Rear |
| 1 | 98.5 | 100.0 | 102.8 | 98.6 | 98.6 | 100.7 | 99.0 | 99.0 | 95.7 | 95.7 | 97.7 | 97.7 | 97.2 | 102.5 | 102.5 | 91.7 | 91.7 | 91.7 | 91.7 | 91.7 | 94.1 |
| 2 | 97.4 | 101.6 | 99.0 | 98.4 | 98.4 | 103.6 | 99.6 | 99.6 | 96.7 | 96.7 | 97.8 | 97.8 | 96.4 | 99.8 | 99.8 | 94.0 | 94.0 | 94.0 | 94.0 | 94.0 | 95.6 |
| 3 | 97.9 | 100.9 | 98.6 | 98.0 | 98.0 | 104.5 | 99.8 | 99.8 | 95.7 | 95.7 | 96.9 | 96.9 | 99.7 | 98.0 | 98.0 | 96.2 | 96.2 | 96.2 | 96.2 | 96.2 | 98.5 |
| 4 | 97.7 | 96.8 | 98.4 | 102.2 | 102.2 | 99.2 | 99.3 | 99.3 | 96.1 | 96.1 | 94.6 | 94.6 | 95.5 | 94.7 | 94.7 | 94.5 | 94.5 | 94.5 | 94.5 | 94.5 | 95.7 |
| 5 | 95.8 | 95.1 | 99.6 | 98.8 | 98.8 | 99.5 | 101.5 | 101.5 | 99.7 | 99.7 | 97.2 | 97.2 | 100.4 | 98.0 | 98.0 | 91.8 | 91.8 | 91.8 | 91.8 | 91.8 | 97.8 |
| 6 | 99.1 | 95.4 | 99.1 | 100.7 | 100.7 | 98.9 | 99.0 | 99.0 | 97.2 | 97.2 | 95.7 | 95.7 | 94.5 | 96.8 | 96.8 | 94.4 | 94.4 | 94.4 | 94.4 | 94.4 | 95.2 |
| Average | 97.7 | 98.3 | 99.6 | 99.5 | 99.5 | 101.1 | 99.7 | 99.7 | 96.9 | 96.9 | 96.7 | 96.7 | 97.3 | 98.3 | 98.3 | 93.8 | 93.8 | 93.8 | 93.8 | 93.8 | 96.2 |
| St Dev. | 1.1 | 2.9 | 1.6 | 1.6 | 1.6 | 2.4 | 0.9 | 0.9 | 1.5 | 1.5 | 1.3 | 1.3 | 2.3 | 2.7 | 2.7 | 1.7 | 1.7 | 1.7 | 1.7 | 1.7 | 1.7 |
| RSD | 1.2 | 2.9 | 1.6 | 1.7 | 1.7 | 2.4 | 0.9 | 0.9 | 1.6 | 1.6 | 1.3 | 1.3 | 2.4 | 2.7 | 2.7 | 1.9 | 1.9 | 1.9 | 1.9 | 1.9 | 1.7 |

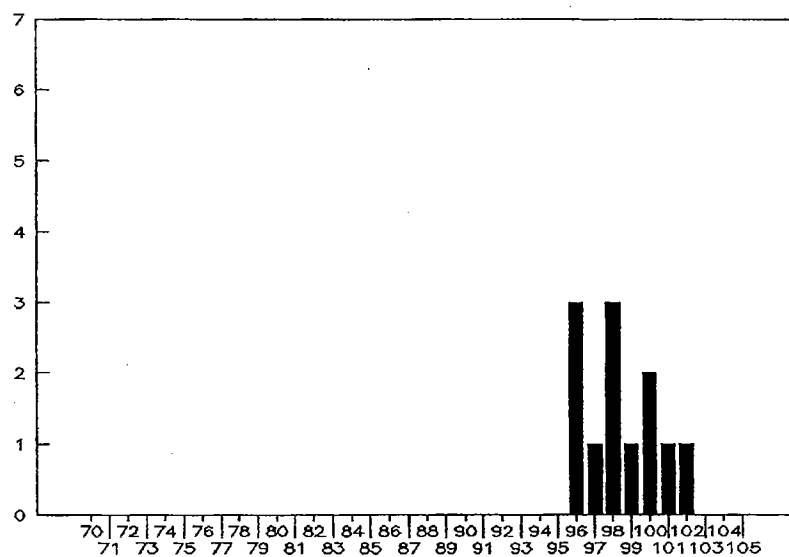
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
15 Min. Dissolution — High kp



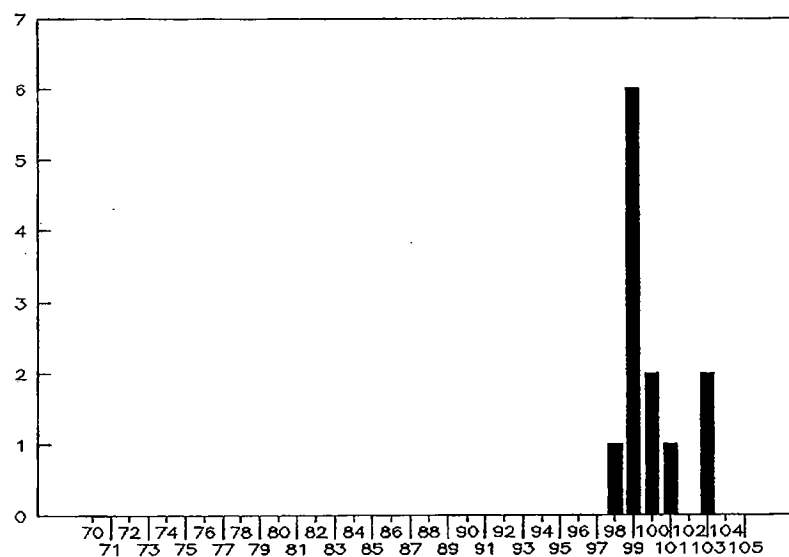
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
15 Min. Dissolution — Low kp



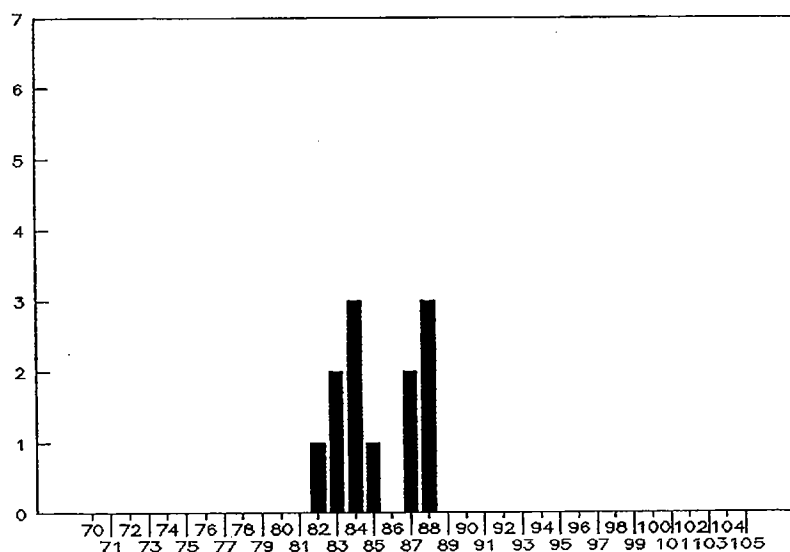
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
60 Min. Dissolution — High kp



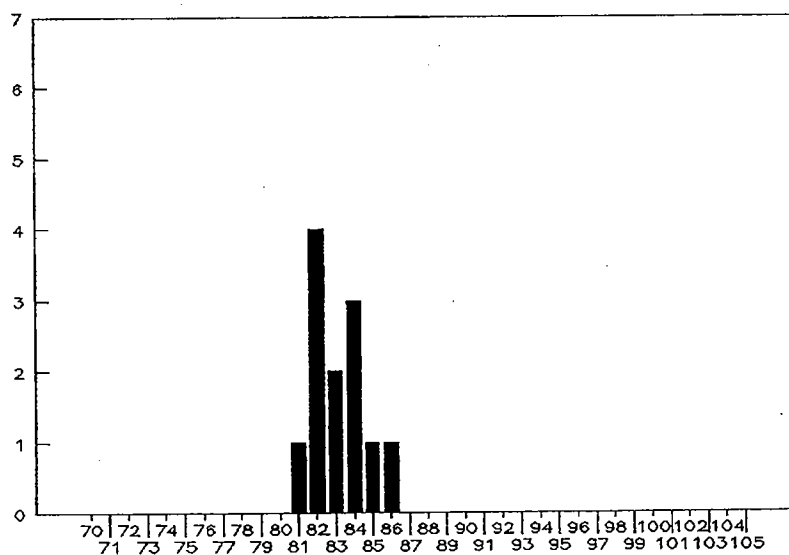
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
60 Min. Dissolution — Low kp



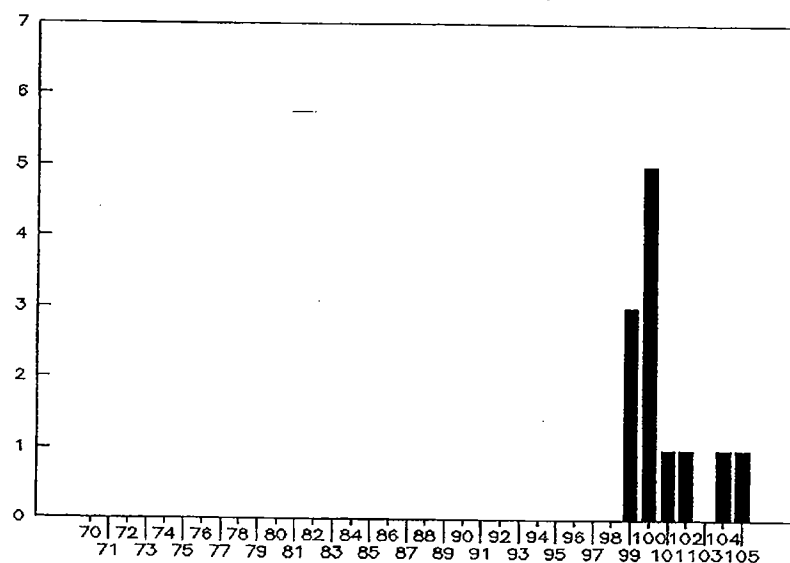
DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
15 Min. Dissolution — High kp



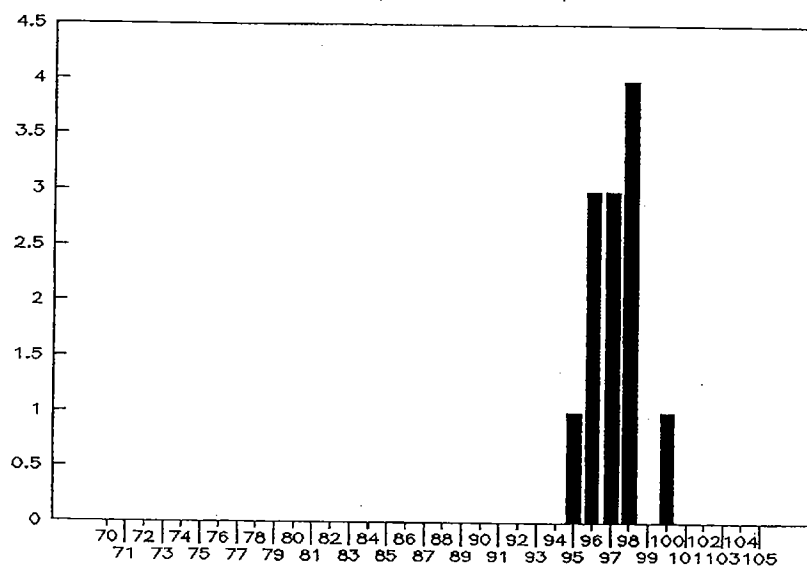
DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
15 Min. Dissolution — Low kp



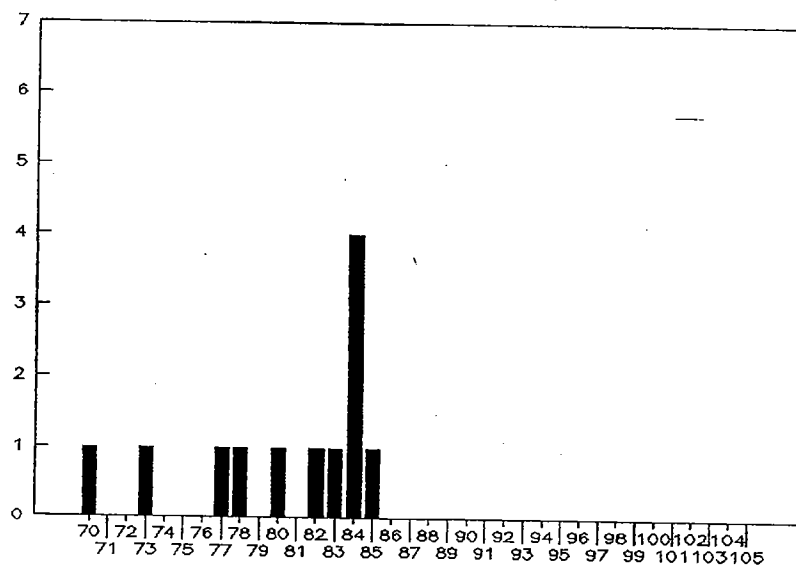
DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
60 Min. Dissolution — High kp



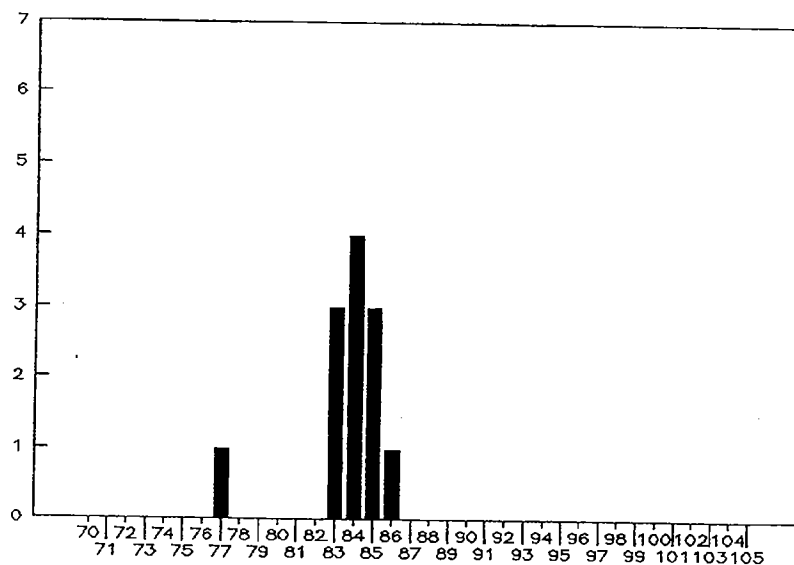
DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
60 Min. Dissolution — Low kp



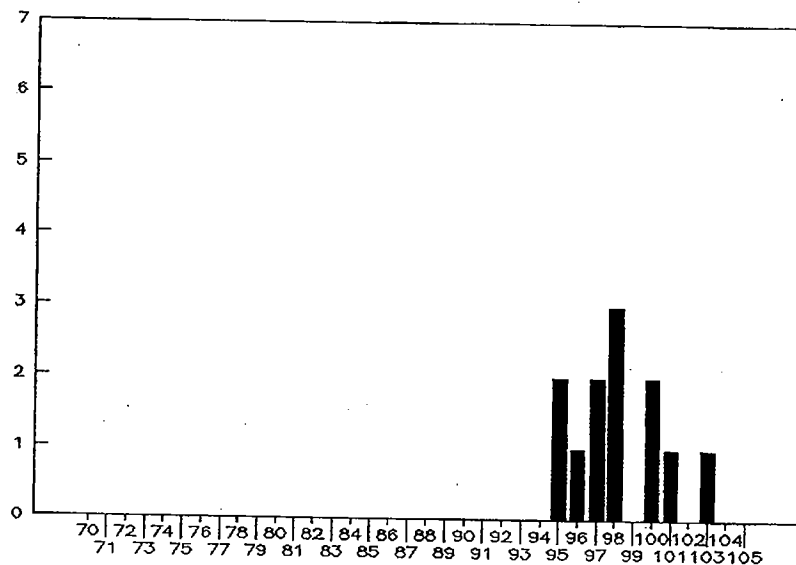
DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
15 Min. Dissolution — High kp



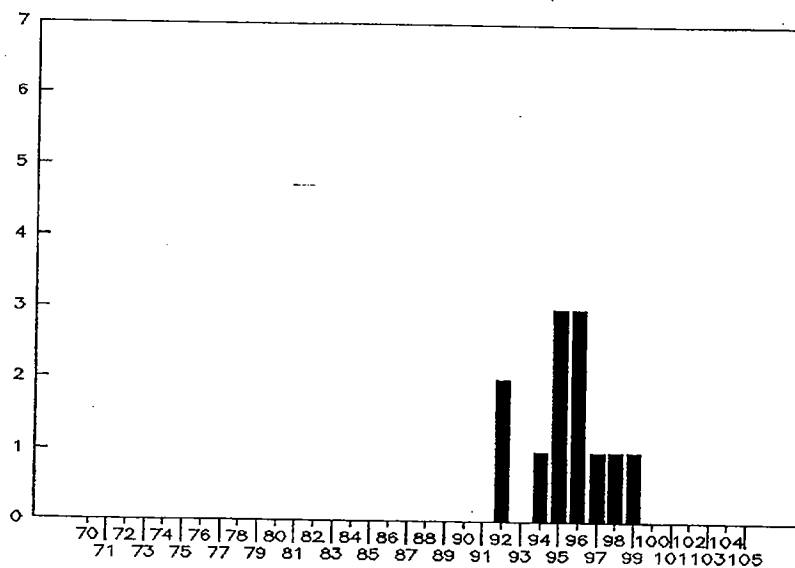
DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
15 Min. Dissolution — Low kp



DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
60 Min. Dissolution — High kp



DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
60 Min. Dissolution — Low kp



Amide Pharmaceutical, Inc.

COMPRESSION DEPARTMENT

PROCESS VALIDATION

PRODUCT NAME: Digoxin Tablets 0.125 Mg (145)BATCH #: 4318 ATABLET PRESS ID #: 66

| | Limit | Time |
|---------------|--------------|----------|
| High KP | above 6 KP | 11.45 Am |
| Low KP | 0.5 - 2.0 KP | 12.16 PM |
| Maximum KP | Not possible | — |
| Regular Speed | 21 RPM | — |

| | RPM | Time |
|------------|-----|----------|
| High Speed | 26 | 12.48 PM |
| Low Speed | 14 | 1.15 PM |

| | |
|--------------------|-----------------------|
| Done By: <u>KP</u> | Date: <u>11/14/94</u> |
|--------------------|-----------------------|

PD301.1

Amide Pharmaceutical, Inc.

Process Validation

Page 1 of 1

COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 4318A

Date: 11/14/94

Tablet Press Id: 66

Hardness Tester Id: 251

Thickness Gauge Id: 646

Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : ~~3.0 - 6.0 KP~~ \Rightarrow 11/3/94

High KP. Above 6. RPM-21

| Front Exit Chute | | | | |
|------------------|----------------|-----------------|----------------|------|
| Time | Weight* (g) | Thickness mm | Hardness KP | Init |
| 11.44 Am | 1.049 | 2.56 | 2.66 | 2.57 |
| 1 Min. | | | 5.2 | 5.8 |
| 11.48 Am | | | 5.2 | 5.6 |
| 5 Min. | 1.054 | 2.57 | 2.57 | 5.2 |
| | | | 5.3 | 4.7 |
| | | | | KP |

| Rear Exit Chute | | | | |
|-----------------|----------------|-----------------|----------------|------|
| Time | Weight* (g) | Thickness mm | Hardness KP | Init |
| 1 Min. | 1.044 | 2.52 | 2.53 | 2.53 |
| | | | 5.1 | 5.0 |
| 5 Min. | 1.052 | 2.55 | 2.60 | 2.58 |
| | | | 5.5 | 5.6 |
| | | | 5.8 | KP |

* Composite Weight of 10 Tablets

| Front Exit Chute | | | | | | | | | |
|------------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | |
| 1 Min. | 104 | 105 | 104 | 104 | 105 | 105 | 106 | 104 | 106 |
| 5 Min. | 106 | 105 | 105 | 106 | 105 | 105 | 104 | 104 | 104 |

| Rear Exit Chute | | | | | | | | | |
|-----------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | |
| 1 Min. | 108 | 105 | 107 | 103 | 106 | 106 | 105 | 106 | 106 |
| 5 Min. | 105 | 103 | 104 | 107 | 107 | 109 | 105 | 104 | 106 |

Comments: Hardness of 6.0 KP and above cannot be achieved. Maximum hardness of 5.8 KP was obtained. At 11.14.94

<PD187.1>

Amide Pharmaceutical, Inc.

Process Validation

Page 1 of 1

COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 4818A

Date: 11/14/11

Tablet Press Id: 66Hardness Tester Id: 251Thickness Gauge Id: 646Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : ~~1.0 - 6.0 KP~~

Leur KP 0.5 - 2.0 RPM - 21.

| Front Exit Chute | | | | |
|------------------|-------------|--------------|-------------|------|
| Time | Weight* (g) | Thickness mm | Hardness KP | Init |
| 12.15 min | 1.049 | 3.12 | 3.09 | 1.0 |
| 1 Min. | | | | |
| 12.19 min | 1.075 | 3.14 | 3.12 | 0.9 |
| 5 Min. | | | | |
| | | | | 1.0 |
| | | | | 1.6 |
| | | | | KP |

| Rear Exit Chute | | | | |
|-----------------|-------------|--------------|-------------|------|
| Time | Weight* (g) | Thickness mm | Hardness KP | Init |
| 1 Min. | 1.044 | 2.98 | 2.99 | 1.4 |
| | | | | 1.3 |
| | | | | 1.5 |
| 5 Min. | 1.054 | 3.06 | 2.99 | 2.99 |
| | | | | 1.9 |
| | | | | 1.5 |
| | | | | 1.7 |
| | | | | KP |

* Composite Weight of 10 Tablets

| Front Exit Chute | | | | | | | | | | |
|------------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | | |
| 1 Min. | 103 | 104 | 105 | 104 | 105 | 106 | 106 | 104 | 105 | 105 |
| 5 Min. | 104 | 110 | 109 | 105 | 110 | 105 | 112 | 112 | 110 | 105 |

| Rear Exit Chute | | | | | | | | | | |
|-----------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | | |
| 1 Min. | 107 | 102 | 103 | 103 | 105 | 103 | 104 | 102 | 102 | 106 |
| 5 Min. | 103 | 104 | 106 | 107 | 106 | 104 | 108 | 107 | 104 | 105 |

Comments:

<PD187.1>

Amide Pharmaceutical, Inc.

Process Validation

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COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 4318A

Date: 11/14/94

Tablet Press Id: 65

Hardness Tester Id: 251

Thickness Gauge Id: 646

Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : 1.0 - 6.0 KP

High Speed 26 RPM

| Front Exit Chute | | | | | | | |
|------------------|----------------|-----------------|------|------|----------------|-----|------|
| Time | Weight* (g) | Thickness mm | | | Hardness KP | | Init |
| 12.47 min | 1.049 | 2.63 | 2.62 | 2.61 | 4.3 | 3.8 | 4.1 |
| 1 Min. | | | | | | | |
| 12.51 min | 1.066 | 2.71 | 2.69 | 2.62 | 4.5 | 4.6 | 4.2 |
| 5 Min. | | | | | | | |

| Rear Exit Chute | | | | | | | | |
|-----------------|----------------|-----------------|------|----------------|-----|------|-----|-----|
| Time | Weight* (g) | Thickness mm | | Hardness KP | | Init | | |
| 1 Min. | 1.058 | 2.62 | 2.58 | 2.64 | 4.4 | 4.5 | 168 | |
| 5 Min. | 1.056 | 2.57 | 2.67 | 2.59 | 4.0 | 4.6 | 5.2 | 168 |

* Composite weight of 10 Tablets

| Front Exit Chute | | | | | | | | | |
|------------------|----------------------------|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet (mg) | | | | | | | | |
| 12.47 min | 105 | 101 | 109 | 107 | 101 | 110 | 106 | 102 | 109 |
| 1 Min. | | | | | | | | | |
| 12.51 min | 105 | 103 | 108 | 102 | 106 | 103 | 106 | 107 | 100 |
| 5 Min. | | | | | | | | | |

| Rear Exit Chute | | | | | | | | | |
|-----------------|----------------------------|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet (mg) | | | | | | | | |
| 1 Min. | 105 | 109 | 110 | 106 | 110 | 105 | 106 | 107 | 104 |
| 5 Min. | 102 | 110 | 107 | 104 | 102 | 103 | 105 | 110 | 103 |

Comments:

Amide Pharmaceutical, Inc.

Process Validation

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COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 4318ADate: 11/14/94Tablet Press Id: 66 Hardness Tester Id: 25/Thickness Gauge Id: 646 Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : 1.0 - 6.0 KP

low speed 14 RPM

| Front Exit Chute | | | | | | | | |
|-------------------|----------------|-----------------|------|------|----------------|-----|------|-----|
| Time | Weight* (g) | Thickness mm | | | Hardness KP | | Init | |
| 1.14 Km 1 Min. | 1.054 | 2.62 | 2.62 | 2.64 | 4.4 | 4.2 | 4.7 | 168 |
| 1.18 Km 5 Min. | 1.057 | 2.62 | 2.64 | 2.65 | 5.2 | 4.4 | 4.9 | 168 |

| Rear Exit Chute | | | | | | | | |
|-----------------|----------------|-----------------|------|----------------|-----|------|-----|-----|
| Time | Weight* (g) | Thickness mm | | Hardness KP | | Init | | |
| 1 Min. | 1-0 63 | 2-67 | 2-64 | 2-64 | 5-0 | 5-0 | 168 | |
| 5 Min. | 1-0 69 | 2-67 | 2-65 | 2-63 | 4-4 | 4-0 | 5-2 | 168 |

* Composite Weight of 10 Tablets

| Front Exit Chute | | | | | | | | | | |
|------------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | | |
| 1 Min. | 106 | 102 | 105 | 106 | 106 | 105 | 104 | 106 | 108 | 105 |
| 5 Min. | 106 | 105 | 108 | 103 | 107 | 107 | 107 | 108 | 105 | 107 |

| Rear Exit Chute | | | | | | | | | | |
|-----------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | | |
| 1 Min. | 107 | 107 | 107 | 106 | 105 | 106 | 108 | 107 | 104 | 105 |
| 5 Min. | 105 | 108 | 107 | 106 | 109 | 107 | 108 | 107 | 105 | 108 |

Comments:

<PD187.1>

Amide Pharmaceutical, Inc.

COMPRESSION DEPARTMENT

PROCESS VALIDATION

PRODUCT NAME: Digoxin Tablets 0.125 mg (145)BATCH #: 4320 ATABLET PRESS ID #: 66

| | Limit | Time |
|---------------|--------------|---------|
| High KP | above 6 KP | 2.50 pm |
| Low KP | 0.5 - 2.0 KP | 3.20 pm |
| Maximum KP | Not Possible | — |
| Regular Speed | 21 RPM | — |

| | RPM | Time |
|------------|-----|---------|
| High Speed | 26 | 3.50 pm |
| Low Speed | 14 | 4.20 pm |

| | |
|--------------------|-----------------------|
| Done By: <u>KP</u> | Date: <u>11/15/94</u> |
|--------------------|-----------------------|

PD301.1

Amide Pharmaceutical, Inc.

Process Validation

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COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 4320A

Date: 11/15/94

Tablet Press Id: 66

Hardness Tester Id: 251

Thickness Gauge Id: 646

Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : 1.0 - 6.0 KP ~~KSP~~ 11/9/94

High KP! Above 6.0 KP RPM 21

| Front Exit Chute | | | | | |
|------------------|----------------|-----------------|----------------|------|-----|
| Time | Weight* (g) | Thickness mm | Hardness KP | Init | |
| 2-49 PM | 1.068 | 2.41 | 2.63 | 2.35 | 6.0 |
| 1 Min. | 1.068 | 2.41 | 2.63 | 2.35 | 6.0 |
| 5-53 PM | 1.069 | 2.58 | 2.60 | 2.36 | 5.8 |
| 5 Min. | 1.069 | 2.58 | 2.60 | 2.36 | 5.8 |

| Rear Exit Chute | | | | | |
|-----------------|----------------|-----------------|----------------|------|-----|
| Time | Weight* (g) | Thickness mm | Hardness KP | Init | |
| 1 Min. | 1.069 | 2.60 | 2.61 | 2.56 | 5.4 |
| 5 Min. | 1.065 | 2.59 | 2.52 | 2.03 | 6.0 |

* Composite Weight of 10 Tablets

| Front Exit Chute | | | | | | | | | |
|------------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | |
| 1 Min. | 106 | 119 | 105 | 104 | 106 | 105 | 105 | 103 | 105 |
| 5 Min. | 106 | 106 | 111 | 104 | 106 | 107 | 103 | 110 | 105 |

| Rear Exit Chute | | | | | | | | | |
|-----------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | |
| 1 Min. | 105 | 103 | 109 | 109 | 107 | 107 | 105 | 107 | 105 |
| 5 Min. | 107 | 107 | 109 | 108 | 103 | 105 | 104 | 105 | 107 |

Comments:

<PD187.1>

Amide Pharmaceutical, Inc.

Process Validation

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COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 4320A Date: 11/15/94Tablet Press Id: 62 Hardness Tester Id: 251Thickness Gauge Id: 646 Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : ~~1.0 - 6.0 KP~~ 1.0 - 6.0 KP 11/9/94
for KP — 0.5 - 2.0 KP RPN - 21

| Front Exit Chute | | | | | | | | |
|------------------|----------------|-----------------|-----|----------------|-----|------|-----|----|
| Time | Weight* (g) | Thickness mm | | Hardness KP | | Init | | |
| 3-29 PM | 1.058 | 3.3 | 3.1 | 3.6 | 1.2 | 1.3 | 1.2 | K1 |
| 1 Min. | | | | | | | | |
| 3-33 PM | | | | | | | | |
| 5 Min. | 1.064 | 3.2 | 3.0 | 2.97 | 1.4 | 1.2 | 1.4 | K1 |

| Rear Exit Chute | | | | | | | | |
|-----------------|----------------|-----------------|------|----------------|-----|------|-----|----|
| Time | Weight* (g) | Thickness mm | | Hardness KP | | Init | | |
| 1 Min. | 1.055 | 3.6 | 2.98 | 3.6 | 1.3 | 2.0 | 1.1 | K8 |
| 5 Min. | 1.053 | 2.98 | 3.03 | 2.98 | 1.1 | 1.7 | 1.4 | K8 |

* Composite Weight of 10 Tablets

| Front Exit Chute | | | | | | | | | | |
|------------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | | |
| 1 Min. | 105 | 108 | 103 | 112 | 104 | 104 | 107 | 105 | 104 | 105 |
| 5 Min. | 108 | 105 | 106 | 103 | 110 | 108 | 107 | 105 | 113 | 103 |

| Rear Exit Chute | | | | | | | | | | |
|-----------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | | |
| 1 Min. | 102 | 107 | 106 | 105 | 102 | 105 | 104 | 108 | 106 | 106 |
| 5 Min. | 106 | 107 | 107 | 104 | 107 | 104 | 108 | 105 | 105 | 106 |

Comments:

<PD187.1>

Amide Pharmaceutical, Inc.

Process Validation

Page 1 of 1COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 4320ADate: 11/15/94Tablet Press Id: 66 Hardness Tester Id: 251Thickness Gauge Id: 646 Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : 1.0 - 6.0 KP

High Speed - 26 RPM

| Front Exit Chute | | | | | | | | |
|------------------|----------------|-----------------|------|----------------|-----|------|-----|----|
| Time | Weight* (g) | Thickness mm | | Hardness KP | | Init | | |
| 3-49 PM | | | | | | | | |
| 1 Min. | 1.013 | 2.53 | 2.55 | 2.63 | 4.5 | 3.0 | 3.4 | KP |
| 3-53 PM | | | | | | | | |
| 5 Min. | 1.000 | 2.56 | 2.40 | 2.53 | 4.4 | 3.5 | 2.2 | KP |

| Rear Exit Chute | | | | | |
|-----------------|----------------|-----------------|----------------|------------|----|
| Time | Weight* (g) | Thickness mm | Hardness KP | Init | |
| 1 Min. | 1.010 | 2.58 2.60 | 2.61 4.2 | 4.0 3.0 | KP |
| 5 Min. | 1.003 | 2.62 2.53 | 2.59 3.2 | 4.4 3.7 | KP |

* Composite Weight of 10 Tablets

| Front Exit Chute | | | | | | | | | |
|------------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | |
| 1 Min. | 100 | 99 | 99 | 107 | 104 | 99 | 100 | 99 | 103 |
| 5 Min. | 106 | 107 | 107 | 95 | 100 | 100 | 102 | 102 | 101 |

| Rear Exit Chute | | | | | | | | | |
|-----------------|---------------------------|----|-----|-----|----|-----|-----|-----|----|
| Time | Weight of Each Tablet(mg) | | | | | | | | |
| 1 Min. | 100 | 99 | 99 | 100 | 99 | 104 | 104 | 105 | 99 |
| 5 Min. | 99 | 99 | 104 | 99 | 99 | 104 | 106 | 105 | 99 |

Comments:

<PD187.1>

COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 4320A

Date: 11/15/94

Tablet Press Id: 66 Hardness Tester Id: 251

Thickness Gauge Id: £46 Scale Id: 235

| | |
|----------------------------|--------------------|
| Target Weight (1 Tablet) | :: 105.0 mg |
| Target Weight (10 Tablets) | :: 1.050 g |
| Weight Range (10 Tablets) | :: 1.019 - 1.082 g |

Thickness Limits : 2.0 - 3.0 mm
Hardness Limits : 1.0 - 6.0 KP

don speed 14 Rpm

| Rear Exit Chute | | | | | | | |
|-----------------|----------------|-----------------|------|------|----------------|-----|------|
| Time | Weight* (g) | Thickness mm | | | Hardness KP | | Init |
| 1 Min. | 1.047 | 2.66 | 2.60 | 2.62 | U-4 | U-5 | K9 |
| 5 Min. | 1.062 | 2.67 | 2.64 | 2.65 | U-3 | U-5 | K9 |

* Composite Weight of 10 Tablets

| Rear Exit Chute | | | | | | | | | | |
|-----------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | | |
| 1 Min. | 103 | 107 | 101 | 107 | 103 | 101 | 101 | 104 | 106 | 106 |
| 5 Min. | 105 | 104 | 106 | 102 | 105 | 104 | 107 | 106 | 105 | 106 |

Comments:

Amide Pharmaceutical, Inc.

COMPRESSION DEPARTMENT

PROCESS VALIDATION

PRODUCT NAME: Digoxin Tablets 0.125 mg (145)BATCH #: 4322 ATABLET PRESS ID #: 66

| | Limit | Time |
|---------------|--------------|---------|
| High KP | above 6 KP | 5.46 pm |
| Low KP | 0.5 - 2.0 KP | 5.58 pm |
| Maximum KP | Not Possible | — |
| Regular Speed | 21 RPM | — |

| | RPM | Time |
|------------|-----|---------|
| High Speed | 26 | 6.10 pm |
| Low Speed | 14 | 6.23 pm |

| | |
|---------------------|-----------------------|
| Done By: <u>K-P</u> | Date: <u>11/17/94</u> |
|---------------------|-----------------------|

PD301.1

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 4322A

Date: 11/18/94

Tablet Press Id: 66 Hardness Tester Id: 251

Thickness Gauge Id: 646 scale Id: 235

| | |
|----------------------------|-------------------|
| Target Weight (1 Tablet) | : 105.0 mg |
| Target Weight (10 Tablets) | : 1.050 g |
| Weight Range (10 Tablets) | : 1.019 - 1.082 g |

Thickness Limits : 2.0 - 3.0 mm

Hardness Limits : ~~1.0 - 5.0 KP~~ 12.5 P 11/11/84

High K^P — Above 6.0 K^P RPM-21

| Front Exit Chute | | | | | | | |
|-------------------|----------------|-----------------|------|------|----------------|-----|------|
| Time | Weight* (g) | Thickness mm | | | Hardness KP | | Init |
| 5.45 hr 1 Min. | 1.064 | 2.66 | 2.59 | 2.60 | 5.8 | 4.9 | 5.5 |
| 5.49 hr 5 Min. | 1.066 | 2.56 | 2.55 | 2.58 | 4.9 | 5.5 | 5.2 |
| | | | | | | | 10.0 |

| Rear Exit Chute | | | | | | | |
|-----------------|----------------|-----------------|------|----------------|-----|------|------|
| Time | Weight* (g) | Thickness mm | | Hardness KP | | Init | |
| 1 Min. | 1.046 | 2.54 | 2.57 | 2.57 | 5.8 | 5.4 | 5.6 |
| 5 Min. | 1.051 | 2.51 | 2.62 | 2.56 | 5.1 | 5.3 | 6.1 |
| | | | | | | | 14.0 |

* Composite Weight of 10 Tablets

| Front Exit Chute | | | | | | | | | | |
|------------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | | |
| 1 Min. | 104 | 104 | 107 | 108 | 104 | 107 | 105 | 105 | 108 | 106 |
| 5 Min. | 106 | 106 | 105 | 106 | 104 | 109 | 100 | 108 | 104 | 108 |

| Rear Exit Chute | | | | | | | | | | |
|-----------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | | |
| 1 Min. | 106 | 107 | 103 | 108 | 105 | 104 | 104 | 109 | 105 | 103 |
| 5 Min. | 107 | 106 | 103 | 103 | 104 | 103 | 104 | 108 | 108 | 107 |

Comments:

Amide Pharmaceutical, Inc.

Process Validation

Page 1 of 1COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 4322ADate: 11/18/94Tablet Press Id: 66Hardness Tester Id: 251Thickness Gauge Id: 646Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : ~~1.0 - 6.0 KP~~ 1.0 - 11/11/94
don't KP — 0.5 - 2.0 KP RPM-21

| Front Exit Chute | | | | | |
|------------------|----------------|-----------------|------|----------------|-----|
| Time | Weight* (g) | Thickness mm | | Hardness KP | |
| 5.57 Min | 1.061 | 3.10 | 3.66 | 0.9 | 0.8 |
| 1 Min. | | | | | |
| 6.01 Min | 1.056 | 3.09 | 3.10 | 1.0 | 1.2 |
| 5 Min. | | | | | |

| Rear Exit Chute | | | | | |
|-----------------|----------------|-----------------|------|----------------|-----|
| Time | Weight* (g) | Thickness mm | | Hardness KP | |
| 1 Min. | 1.047 | 3.12 | 3.69 | 0.9 | 1.1 |
| 5 Min. | 1.053 | 3.05 | 3.04 | 3.06 | 1.2 |
| | | | | | |

* Composite Weight of 10 Tablets

| Front Exit Chute | | | | | | | | | |
|------------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | |
| 1 Min. | 107 | 104 | 102 | 106 | 104 | 106 | 106 | 107 | 108 |
| 5 Min. | 103 | 107 | 107 | 108 | 106 | 106 | 105 | 105 | 107 |

| Rear Exit Chute | | | | | | | | | |
|-----------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | |
| 1 Min. | 103 | 106 | 104 | 108 | 104 | 106 | 103 | 102 | 103 |
| 5 Min. | 109 | 103 | 102 | 102 | 105 | 108 | 104 | 105 | 106 |

Comments:

<P0187.1>

Amide Pharmaceutical, Inc.

Process Validation

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COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 4322A Date: 11/18/04Tablet Press Id: C6 Hardness Tester Id: 251Thickness Gauge Id: C46 Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : 1.0 - 6.0 KP

High Speed - 26 RPM

| Front Exit Chute | | | | | |
|------------------|----------------|-----------------|----------------|------|-----|
| Time | Weight* (g) | Thickness mm | Hardness KP | Init | |
| 1 Min. | 1.000 | 2.50 | 2.52 | 2.53 | 2.5 |
| 5 Min. | 0.986 | 2.52 | 2.50 | 2.51 | 3.1 |

| Rear Exit Chute | | | | | |
|-----------------|----------------|-----------------|----------------|------|-----|
| Time | Weight* (g) | Thickness mm | Hardness KP | Init | |
| 1 Min. | 0.979 | 2.61 | 2.52 | 2.52 | 3.4 |
| 5 Min. | 1.001 | 2.51 | 2.57 | 2.50 | 2.8 |

* Composite Weight of 10 Tablets

| Front Exit Chute | | | | | | | | | | |
|------------------|---------------------------|-----|----|-----|----|----|-----|----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | | |
| 1 Min. | 95 | 93 | 95 | 100 | 98 | 98 | 100 | 99 | 100 | 99 |
| 5 Min. | 105 | 106 | 96 | 101 | 99 | 94 | 99 | 98 | 97 | 100 |

| Rear Exit Chute | | | | | | | | | | |
|-----------------|---------------------------|-----|----|-----|----|----|-----|-----|----|----|
| Time | Weight of Each Tablet(mg) | | | | | | | | | |
| 1 Min. | 101 | 102 | 99 | 105 | 98 | 96 | 98 | 100 | 99 | 95 |
| 5 Min. | 102 | 99 | 93 | 99 | 99 | 97 | 100 | 101 | 99 | 98 |

Comments:

<P0187.1>

Amide Pharmaceutical, Inc.

Process Validation

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COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 4322ADate: 11/18/94Tablet Press Id: 66 Hardness Tester Id: 251Thickness Gauge Id: 246 Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : 1.0 - 6.0 KP

low Speed - 14 RPM

| Front Exit Chute | | | | | |
|------------------|----------------|--------------------|----------------|-----|------|
| Time | Weight* (g) | Thickness mm | Hardness KP | | Init |
| 1 Min. | 1.050 | 2.62 2.64 2.65 | 4.3 | 5.2 | 4.4 |
| 5 Min. | 1.058 | 2.66 2.65 2.64 4.7 | 4.5 | 4.1 | 4.0 |

| Rear Exit Chute | | | | | |
|-----------------|----------------|-----------------|----------------|-----|------|
| Time | Weight* (g) | Thickness mm | Hardness KP | | Init |
| 1 Min. | 1.069 | 2.63 2.61 2.60 | 5.0 | 4.1 | 4.5 |
| 5 Min. | 1.082 | 2.62 2.71 2.63 | 4.5 | 4.9 | 6.2 |

* Composite Weight of 10 Tablets

| Front Exit Chute | | | | | | | | | |
|------------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | |
| 1 Min. | 105 | 107 | 106 | 104 | 103 | 107 | 105 | 104 | 108 |
| 5 Min. | 103 | 106 | 106 | 104 | 106 | 104 | 104 | 105 | 106 |

| Rear Exit Chute | | | | | | | | | |
|-----------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | |
| 1 Min. | 110 | 105 | 106 | 109 | 106 | 106 | 107 | 108 | 104 |
| 5 Min. | 108 | 107 | 109 | 106 | 110 | 111 | 106 | 110 | 108 |

Comments:

<0187.1>

Amide Pharmaceutical, Inc.

Page 1 of 2

LABORATORY TEST REPORT

FINISHED DRUG PRODUCT

PRODUCT: Digoxin Tablets 0.125 mgSPECIFICATION: USPCONTROL #: 4318ACHEMIST: S. J/PKVOLUME #: 318 02/31/04PAGE #: 27/211DATE: 11/17/94SAMPLE STAGE: Overall Comparison Bid: 11/16/94

| TEST | RESULT | LIMIT |
|--|---|--|
| DESCRIPTION: Color: | <u>Yellow</u> | Yellow |
| Profile: | <u>Round Bisected Tablets</u> | Round Bisected Tablets |
| Other: Debossed | <u>"A 145" on bisected side of the tablet</u> | "A 145" on bisected side of the tablet |
| THICKNESS: (Guideline) | <u>2.6 mm</u> | 2.0 mm to 3.0 mm |
| WEIGHT VARIATION: | <u>105.3 mg</u> | ± 10% Theo. wt (105 mg) 94.5 mg - 115.5 mg |
| FRIABILITY: | <u>0.02 %</u> | NMT 1.0 % |
| IDENTIFICATION: (A) | <u>The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation</u> | The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation. |
| ASSAY: Digoxin, 0.125 mg | <u>100.0 %</u> | 90.0% to 105.0% |
| UNIFORMITY OF DOSAGE UNITS: (Content Uniformity) | 1) <u>102.3 %</u> 6) <u>101.6 %</u> 2) <u>104.6 %</u> 7) <u>100.4 %</u> 3) <u>103.9 %</u> 8) <u>101.6 %</u> 4) <u>100.5 %</u> 9) <u>100.7 %</u> 5) <u>99.9 %</u> 10) <u>101.7 %</u> AV: <u>101.7 %</u> RSD: <u>1.5 %</u> | 85.0% to 115.0% |
| <input checked="" type="checkbox"/> COMPLIES <input type="checkbox"/> DOES NOT COMPLY | PREPARED BY: <u>Milena Patel</u> APPROVED BY: <u>Suzanne Patel</u> | DATE: <u>11/17/94</u> DATE: <u>11/17/94</u> RSD: NMT 6.0% |

0013-145c

Pharmaceutical, Inc.

Page 2 of 2

LABORATORY TEST REPORT**FINISHED DRUG PRODUCT**PRODUCT: Digoxin Tablets, 0.125 mgSPECIFICATION: USPCONTROL #: 4318ACHEMIST: S.J./P.K.
H.D.VOLUME #: 918.02/321-07 PAGE #: 27/211DATE: 11/17/99SAMPLE STAGE: Overall Composite Dot: 11/16/99

| TEST | RESULT | LIMIT |
|--|--|---|
| DISSOLUTION: Media: 500mL 0.1N HCl Appar: I, rpm: 120 Temp: 37°C ± 0.5°C Time: 60 minutes | 15 minutes: 1) <u>95.8</u> % 7) <u>95.6</u> % 2) <u>93.0</u> % 8) <u>91.9</u> % 3) <u>91.6</u> % 9) <u>92.5</u> % 4) <u>93.1</u> % 10) <u>95.0</u> % 5) <u>95.3</u> % 11) <u>94.6</u> % 6) <u>91.7</u> % 12) <u>98.1</u> % Average: <u>93.1</u> % 60 minutes: 1) <u>100.3</u> % 7) <u>99.4</u> % 2) <u>100.0</u> % 8) <u>95.1</u> % 3) <u>97.2</u> % 9) <u>97.9</u> % 4) <u>96.6</u> % 10) <u>98.4</u> % 5) <u>101.3</u> % 11) <u>100.6</u> % 6) <u>99.9</u> % 12) <u>99.6</u> % Average: <u>98.9</u> % | (Note - The specified tolerances are for % dissolved, and are not to be interpreted as Q values.) NLT 80% of the LC of Digoxin dissolved in 60 minutes for the average of 12 tablets tested and no individual tablet has less than 75% of the LC of Digoxin dissolved in 60 minutes. If the amount of Digoxin dissolved in 60 minutes is more than 95% for any individual Tablet, the amount dissolved in 15 minutes is not more than 90% for each individual Tablet. (LC: Labeled amount) |
| <input checked="" type="checkbox"/> COMPLIES <input type="checkbox"/> DOES NOT COMPLY | PREPARED BY: <u>Milesh Patel</u> DATE: <u>11/17/99</u> APPROVED BY: <u>Suryakant Patel</u> DATE: <u>11/17/99</u> | <div style="border: 1px solid black; padding: 5px; text-align: center;"> APPROVED BY <u>S.D.</u> DATE <u>11/17/99</u> </div> |

QC13-145d

Amide Pharmaceutical, Inc.

Page 1 of 2

LABORATORY TEST REPORT**FINISHED DRUG PRODUCT**PRODUCT: Digoxin Tablets 0.125 mgSPECIFICATION: USPCONTROL #: 41320ACHEMIST: NP/PKVOLUME #: 306-02/321-04 PAGE #: 25/213DATE: 11/17/94SAMPLE STAGE: over all compenite dated 11/16/94

| TEST | RESULT | LIMIT |
|--|---|---|
| DESCRIPTION: Color: | <u>Yellow</u> | Yellow |
| Profile: | <u>Round bisected Tablets</u> | Round Bisected Tablets |
| Other: Debossed | <u>"A 145" on bisected side of the tablet</u> | "A 145" on bisected side of the tablet |
| THICKNESS: (Guideline) | <u>2.6 mm</u> | 2.0 mm to 3.0 mm |
| WEIGHT VARIATION: | <u>104.9 mg.</u> | ± 10% Theo. wt (105 mg) 94.5 mg - 115.5 mg |
| FRIABILITY: | <u>0.02 %</u> | NMT 1.0 % |
| IDENTIFICATION: (A) | <u>The retention time of the major peak in the chromatogram of Assay Prep. corresponds to standard prep.</u> | The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation. |
| ASSAY: Digoxin, 0.125 mg | <u>100.61</u> | 90.0% to 105.0% |
| UNIFORMITY OF DOSAGE UNITS: (Content Uniformity) | 1) <u>99.9 %</u> 6) <u>100.7 %</u> 2) <u>106.2 %</u> 7) <u>99.8 %</u> 3) <u>99.7 %</u> 8) <u>99.9 %</u> 4) <u>100.2 %</u> 9) <u>100.3 %</u> 5) <u>101.2 %</u> 10) <u>102.7 %</u> AV: <u>100.5</u> RSD: <u>0.91</u> | 85.0% to 115.0% <div style="border: 2px solid black; padding: 5px; display: inline-block;"> APPROVED <u>MSD</u> <u>DATE: 11/17/94</u> </div> RSD: NMT 6.0% |
| (✓) COMPLIES | PREPARED BY: <u>Nilegh Patel</u> | DATE: <u>11/1/94</u> |
| () DOES NOT COMPLY | APPROVED BY: <u>Suzanne Patel</u> | DATE: <u>11/1/94</u> |

QC13-145c

Aide Pharmaceutical, Inc.

Page 2 of 2

LABORATORY TEST REPORT**FINISHED DRUG PRODUCT**PRODUCT: Digoxin Tablets, 0.125 mgSPECIFICATION: USPCONTROL #: 4320ACHEMIST: K.K.VOLUME #: 325.01PAGE #: 177DATE: 11/19/94SAMPLE STAGE: over all complete

| TEST | RESULT | LIMIT |
|--|--|---|
| DISSOLUTION: Media: 500mL 0.1N HCl Appar: I, rpm: 120 Temp: 37°C ± 0.5°C Time: 60 minutes | 15 minutes: 1) <u>81.0</u> % 7) <u>80.8</u> % 2) <u>81.7</u> % 8) <u>80.0</u> % 3) <u>82.1</u> % 9) <u>79.5</u> % 4) <u>81.7</u> % 10) <u>85.6</u> % 5) <u>82.3</u> % 11) <u>81.5</u> % 6) <u>81.8</u> % 12) <u>84.6</u> % Average: <u>81.7</u> % 60 minutes: 1) <u>99.1</u> % 7) <u>100.5</u> % 2) <u>98.7</u> % 8) <u>98.2</u> % 3) <u>98.3</u> % 9) <u>98.4</u> % 4) <u>97.1</u> % 10) <u>101.8</u> % 5) <u>98.4</u> % 11) <u>96.5</u> % 6) <u>95.9</u> % 12) <u>99.5</u> % Average: <u>98.7</u> % | (Note - The specified tolerances are for % dissolved, and are not to be interpreted as Q values.) NLT 80% of the LC of Digoxin dissolved in 60 minutes for the average of 12 tablets tested and no individual tablet has less than 75% of the LC of Digoxin dissolved in 60 minutes. If the amount of Digoxin dissolved in 60 minutes is more than 95% for any individual Tablet, the amount dissolved in 15 minutes is not more than 90% for each individual Tablet. (LC: Labeled amount) |
| <input checked="" type="checkbox"/> COMPLIES <input type="checkbox"/> DOES NOT COMPLY | PREPARED BY: <u>Mitch Hede</u> DATE: <u>11/17/94</u> APPROVED BY: <u>Suey-Qua T. Pugh</u> DATE: <u>11/19/94</u> | <div style="border: 1px solid black; padding: 5px; text-align: center;"> APPROVED <u>W.S.A.</u> DATE <u>11/19/94</u> </div> |

QC13-145d

Amide Pharmaceutical, Inc.

Page 1 of 2

LABORATORY TEST REPORTFINISHED DRUG PRODUCTPRODUCT: Digoxin Tablets 0.125 mgSPECIFICATION: USPCONTROL #: 7322ACHEMIST: NP/PKVOLUME #: 1321-04PAGE #: 1220DATE: 11/21/94SAMPLE STAGE: Overall composite of Batch Dated 11/18/94

| TEST | RESULT | LIMIT |
|--|---|--|
| DESCRIPTION: Color: | <u>Yellow</u> | Yellow |
| Profile: | <u>Round bisected tablets</u> | Round Bisected Tablets |
| Other: Debossed | <u>"A 145" on bisected side of the tablet</u> | "A 145" on bisected side of the tablet |
| THICKNESS: (Guideline) | <u>2.6</u> | 2.0 mm to 3.0 mm |
| WEIGHT VARIATION: | <u>105.4 mg</u> | ± 10% Theo. wt (105 mg) 94.5 mg - 115.5 mg |
| FRIABILITY: | <u>0.1 %</u> | NMT 1.0 % |
| IDENTIFICATION: (A) | <u>The retention time of the major peak in the chromatogram of Assay prep. corresponds to standard preparation.</u> | The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation. |
| ASSAY: Digoxin, 0.125 mg | <u>100.81</u> | 90.0% to 105.0% |
| UNIFORMITY OF DOSAGE UNITS: (Content Uniformity) | 1) <u>100.1</u> % 6) <u>98.5</u> % 2) <u>99.4</u> % 7) <u>97.8</u> % 3) <u>98.9</u> % 8) <u>99.9</u> % 4) <u>99.6</u> % 9) <u>98.4</u> % 5) <u>100.5</u> % 10) <u>99.8</u> % AV: <u>99.1</u> RSD: <u>0.91</u> | 85.0% to 115.0% |
| (<input checked="" type="checkbox"/>) COMPLIES | PREPARED BY: <u>Milena Patel</u> | DATE: <u>11/17/94</u> |
| () DOES NOT COMPLY | APPROVED BY: <u>Suzanne Patel</u> | DATE: <u>11/17/94</u> |



RSD: NMT 6.0%

QC13-145c

Je Pharmaceutical, Inc.

Page 2 of 2

LABORATORY TEST REPORT**FINISHED DRUG PRODUCT**PRODUCT: Digoxin Tablets, 0.125 mgSPECIFICATION: USPCONTROL #: 4322ACHEMIST: K.K.VOLUME #: 325.01PAGE #: 204DATE: 11/21/94SAMPLE STAGE: over all composite of batches

| TEST | RESULT | LIMIT |
|--|--|---|
| DISSOLUTION: Media: 500mL 0.1N HCl Appar: I, rpm: 120 Temp: 37°C ± 0.5°C Time: 60 minutes | 15 minutes: 1) <u>78.4</u> % 7) <u>84.3</u> % 2) <u>79.9</u> % 8) <u>83.9</u> % 3) <u>78.9</u> % 9) <u>80.3</u> % 4) <u>77.7</u> % 10) <u>82.5</u> % 5) <u>79.0</u> % 11) <u>81.4</u> % 6) <u>77.9</u> % 12) <u>81.0</u> % Average: <u>80.4</u> % 60 minutes: 1) <u>97.4</u> % 7) <u>98.2</u> % 2) <u>98.9</u> % 8) <u>98.4</u> % 3) <u>95.2</u> % 9) <u>95.0</u> % 4) <u>95.8</u> % 10) <u>95.7</u> % 5) <u>94.8</u> % 11) <u>99.2</u> % 6) <u>96.0</u> % 12) <u>93.6</u> % Average: <u>96.5</u> % | (Note - The specified tolerances are for % dissolved, and are not to be interpreted as Q values.) NLT 80% of the LC of Digoxin dissolved in 60 minutes for the average of 12 tablets tested and no individual tablet has less than 75% of the LC of Digoxin dissolved in 60 minutes. If the amount of Digoxin dissolved in 60 minutes is more than 95% for any individual Tablet, the amount dissolved in 15 minutes is not more than 90% for each individual Tablet. (LC: Labeled amount) |
| <div style="border: 1px solid black; padding: 5px; width: fit-content;"> APPROVED BY <u>S.A.</u> DATE <u>11/21/94</u> </div> | | |
| <input checked="" type="checkbox"/> COMPLIES <input type="checkbox"/> DOES NOT COMPLY | PREPARED BY: <u>Nilesh Patel</u> DATE: <u>11/17/94</u> APPROVED BY: <u>Sweyachal Patel</u> DATE: <u>11/18/94</u> | |

QC13-145d

Protocol No. 001

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL

DIGOXIN TABLETS 0.125 mg
MPR NO. 14502 REV. 00

BATCH SIZE: 1,600,000 TABLETS

PREPARED BY:

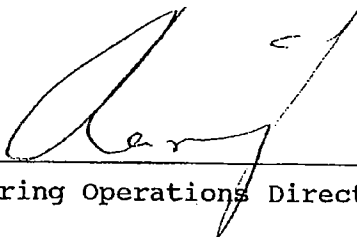


Regulatory Affairs Director

DATE:

11/2/94

APPROVED BY:



Manufacturing Operations Director

DATE:

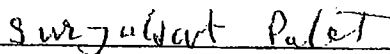
11/3/94



Quality Assurance Director

DATE:

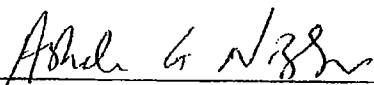
11/2/94



Quality Control Director

DATE:

11/2/94



Vice President Operations

DATE:

11-2-94

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.125 mg
MPR NO. 14502 REV.00

PURPOSE:

This document provides the procedure to be followed to validate the manufacturing process for Digoxin Tablets 0.125 mg. It applies to the next three consecutive batches to be produced.

SCOPE:

This protocol is designed to be prospective in nature.

The guidelines presented here include all steps of the manufacturing process which may have an impact on product quality. They are as follows:

Raw Materials
Blending
Compression

Details of the process will be found in the completed copies of the Manufacturing Batch Records which are available in the file. A summary of the process is found on the attached flow chart. The major equipment used will be documented and monitored as described in the appropriate section below.

Temperature and humidity will be monitored in the production area on a daily basis.

2% excess of Digoxin is added in the finished product to compensate for production losses.

The data gathered during the course of this study will be evaluated and any adjustments to the predetermined specifications or guidelines will be made as warranted based on the results of the three validation batches.

PROCEDURE:

RAW MATERIALS

All raw materials used in a validation batch will be certified to meet all current Amide specifications for that item. These will specifically include particle size profile, bulk density, and tamped density.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.125 mg
MPR NO. 14502 REV.00

Certification may be accomplished through direct testing by Amide, or an approved contract laboratory, or through a manufacturers Certificate of Analysis.

Digoxin, USP will be tested by Amide, or an approved contract laboratory for the complete monograph. This will include bulk density, tamped density, and particle size testing.

The excipients will be tested by Amide, or an approved contract laboratory, for those parameters required for expired stock retesting. In addition, particle size, bulk and tamped density will be run on all ingredients. The other results may be taken from the manufacturers COA.

In addition to the actual results, the name of the manufacturer, and the manufacturers lot number should be included in the report.

If more than one lot of a raw material is used in the production of the three batches the data should be evaluated to determine if any differences are detectable.

The acceptance criteria will be the specification limits for those tests listed in the Specification document.

BLENDING UNIFORMITY

The preblend will be produced in the 3 cu.ft. Twin Shell Blender, (#32). The speed will be monitored and documented both empty and during blending.

The blend in this step will be subjected to further processing, no sampling will be taken at this point.

The final blend will be produced in the 10 Cu Ft. Twin Shell Blender, (#35). The speed will be monitored and documented both empty and during blending.

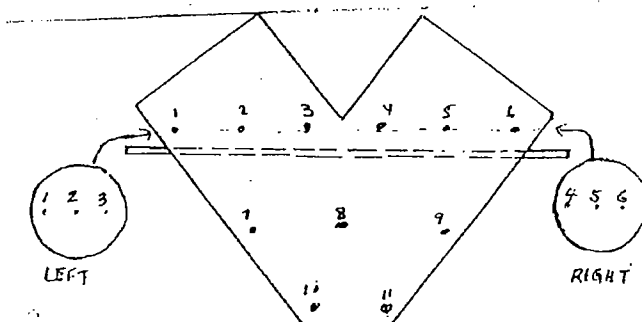
The sampling plan for the final blend is designed to evaluate overall blend uniformity, and those points in the blender where uniformity is most difficult to achieve. Samples are to be taken from the points shown below using only the 36 inch (small chamber) single port thief. The sample drawn should be about 315 mg which is three times the single dosage unit, and should be submitted to the laboratory in "Butter Paper."

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.125 mg
MPR NO. 14502 REV.00

SAMPLING POINTS

- | | |
|------------------------------|--------------------|
| 1. Left Column - Top left | 7. Middle - Left |
| 2. Left Column - Top Center | 8. Middle - Center |
| 3. Left Column - Top Right | 9. Middle - Right |
| 4. Right Column - Top left | 10. Bottom - Left |
| 5. Right Column - Top Center | 11. Bottom - Right |
| 6. Right Column - Top Right | |



The samples are to be analyzed individually, without being ground, for Digoxin. No composite samples are to be prepared. The sample weight used for analysis should approximate 105 mg, which is the amount of this blend which would be present in one unit of the tablet.

Acceptance criteria is 85.0 - 115.0 % Th for the individual data points. This product has a 2% overage to compensate for the production losses.

Scarf *10/11/11* *10/11/11*
Three sample of about 150 g will be taken with the help of a stainless steel ~~large chamber~~ *large chamber* from the top center, middle center and bottom center of the blender. This sample will be tested for physical characterization which includes; bulk and tap density and particle size analysis. This data is for characterization only and these parameters will not be used to monitor routine production. Therefore, acceptance criteria will not be established.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.125 mg
MPR NO. 14502 REV.00

COMPRESSION

Compression will be accomplished using the stokes 45 station tablet press. The speed will be determined and documented during the validation study.

During compression samples will be collected every 30 minutes hour by QA. These samples will be evaluated for individual tablet weight, thickness, and hardness. This will be 10 tablets for weight, and five each for thickness and hardness. Front and rear samples will be tested separately and will not be composited for any test in this section unless specifically stated.

The 30 minute samples should be arranged chronologically and the batch divided into thirds. Each third should be evaluated as described below for all tests except content uniformity. The samples for each test should be prepared by selecting, as close as possible, an equal number of tablets from each 30 minute sample. If selecting one tablet per hour results in a greater number of tablets than the test requires the distribution should be as even as possible.

| TEST | N |
|----------------|-----------------------|
| Friability | 10 g - 1 Run |
| Disintegration | 6 |
| Dissolution | 12 (6 front & 6 rear) |

Content Uniformity testing is to be run across the entire batch. One tablet per 30 minute sample is to be run with a minimum of 30 tablets being required. The tablets selected for testing should be weighed prior to testing and their identity maintained. If compression runs for less than 15 hours, the additional tablets should be selected as evenly distributed as possible throughout the batch.

A portion of the blend will be run at hardness of 0.5 - 2.0 KP and above 6.0 KP. This will determine the effect of hardness on friability and dissolution.

Minimum quantities sufficient to equilibrate the press will be run at both lower and higher speeds. The actual ranges will be determined during production. Samples will be evaluated for hardness and weight.

Data analysis will consist of Average and Standard Deviation, with comparison both within and across the three batches. The data collected within each batch will also be evaluated for any possible trends.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.125 mg
MPR NO. 14502 REV.00

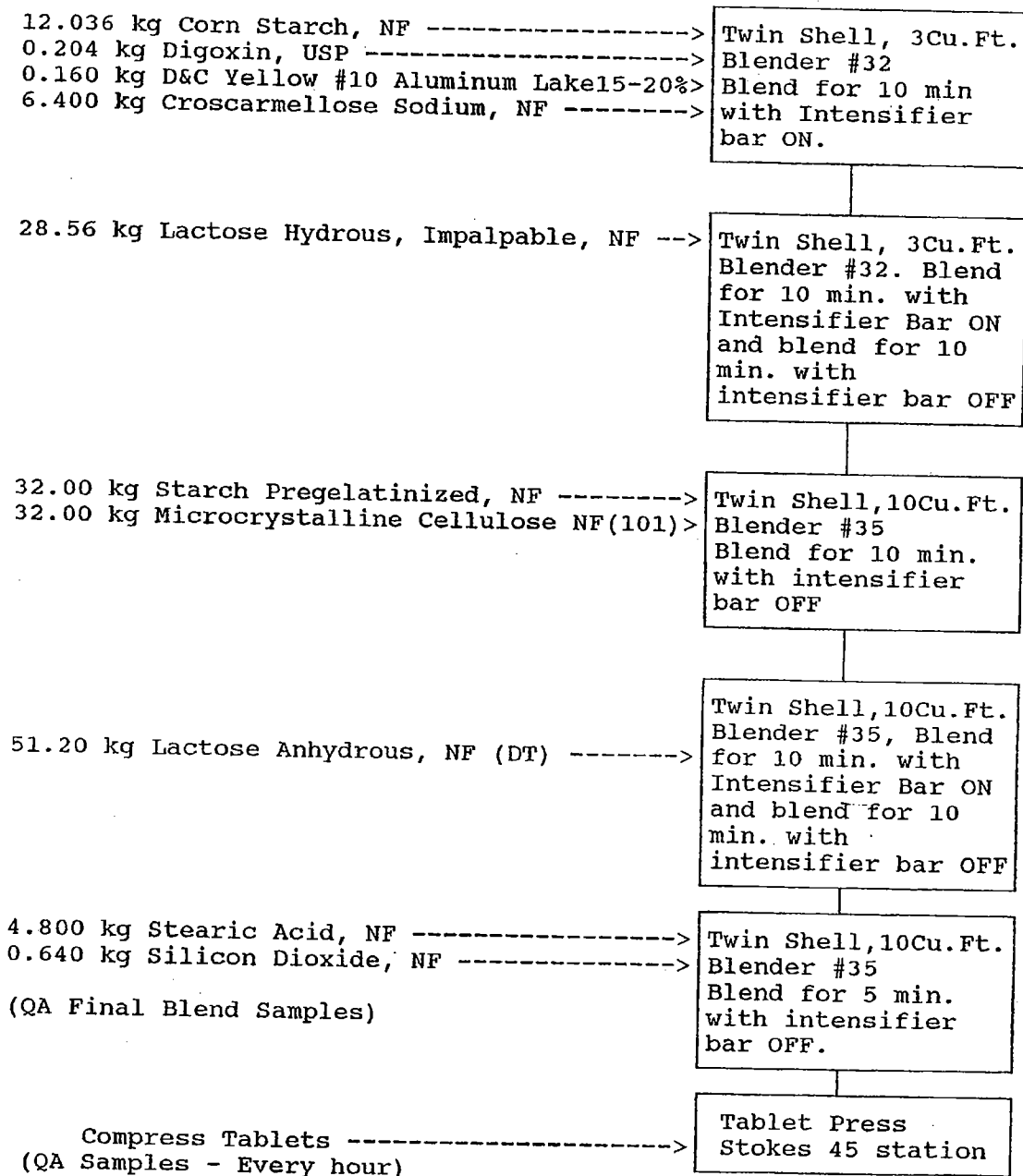
An overall composite sample will be prepared from all the 30 minute samples. This data will provide the basis for product release and will also be the initial data for stability.

Acceptance criteria will be as follows:

| | |
|-----------------------------|-------------------------------|
| Target Weight (1 tablet): | 105.0 mg |
| Target Weight (10 tablets): | 1.050 g |
| Weight Range (1 tablet): | 0.097 - 0.113 g |
| Thickness: | 2.0 - 3.0 mm |
| Hardness: | 1.0 - 6.0 KP |
| Friability | NMT 1% |
| Identification | Meets requirements. |
| Content Uniformity | 85.0% - 115.0% (RSD NMT 6.0%) |
| Dissolution | Meets USP Requirement. |
| Assay | 90.0 - 105.0% |

AMIDE PHARMACEUTICAL, INC.

BATCH FLOW CHART FOR DIGOXIN TABLETS 0.125 mg
 BATCH SIZE: 1,600,000 TABLETS
 MPR # 14502, REV # 00



PROCESS VALIDATION REPORT
ADDENDUM NO. 01

DIGOXIN TABLETS, 0.125 mg
AMIDE PHARMACEUTICAL, INC.
BATCHES 4318A, 4320A, and 4322A
BATCH SIZE: 1,600,000 TABLETS

MPR NO. 14502

Revision No. 00

Prepared by: RLW

Date Prepared: 2/16/95

Approved by:

Ashde G. Nigal
VP Operations

Date: 2-16-95

Ashde G. Nigal
Manufacturing Operations Director

Date: 2-16-95

Adrianne B. [Signature]
Regulatory Affairs Director

Date: 2/16/95

Suzanne A. Puleo
Quality Control Director

Date: 2/16/95

RLW
Quality Assurance Director

Date: 2/16/95

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION SUMMARY
ADDENDUM NO. 01

PRODUCT DIGOXIN TABLETS, 0.125 mg

BATCH 4318A
4320A
4322A

This addendum is being issued to clarify the allowable press speed limits. As stated in the report, unacceptable weight variability was observed during the high speed validation run. Acceptable results were obtained between 14 and 21 rpm. It should be noted that 21 is the normal speed for this product.

At this time the allowable range will be 14 - 21 rpm. Additional work will be done during future production to better define the upper limit.

PROCESS VALIDATION REPORT
ADDENDUM NO. 02

DIGOXIN TABLETS, 0.125 mg
AMIDE PHARMACEUTICAL, INC.
BATCHES 5068A, 5069A, and 5070A
BATCH SIZE: 1,600,000 TABLETS

MPR NO. 14502

Revision No. 00

Prepared by:

KRW

Date Prepared:

3/28/95

Approved by:

Ashley G. N. 3/28

VP Operations

Date:

3-29-95

Carry
Manufacturing Operations Director

Date:

3-29-95

Adrian B. B.
Regulatory Affairs Director

Date:

3/29/95

Deborah L. S. B. 3/29/95
Quality Control Director

Date:

3/29/95

KRW
Quality Assurance Director

Date:

3/29/95

PRODUCT DIGOXIN TABLETS, 0.125 mg

BATCH 5068A
5069A
5070A

This addendum is being issued to document the additional work done to more accurately define the upper press speed limit, as described in Addendum 01 to the validation report.

The three batches listed above were run for a short period at 28 rpm with the weight set as close as possible to theoretical. The data is attached and is all within acceptable limits.

Therefore, the allowable range for press speed will be 14 - 28 rpm. Note that the normal speed for this product is 21 rpm.

Amide Pharmaceutical, Inc.

COMPRESSION DEPARTMENT
PROCESS VALIDATION

PRODUCT NAME: Digoxin Tablets 0.125 mg (145)BATCH #: 5068ATABLET PRESS ID #: 67

| | Limit | Time |
|---------------|---------------|------|
| High RP | | |
| Low RP | N/A AN 3-7-95 | |
| Maximum RP | | |
| Regular Speed | | |

| | RPM | Time |
|------------|---------------|--|
| High Speed | 28 | 1.37 Run - 2.55 Run ^{12.0 3/5/95} |
| Low Speed | N/A AN 3-7-95 | — |

| | |
|----------------------|---------------------|
| Done By: <u>K. D</u> | Date: <u>3/7/95</u> |
|----------------------|---------------------|

10101.1

Amide Pharmaceutical, Inc.

Process Validation

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COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 5068A

Date: 3/7/95

Tablet Press Id: 67 Hardness Tester Id: 254

Thickness Gauge Id: 642 Scale Id: 226

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : 1.0 - 6.0 KP

High Speed RPM 28

| Front Exit Chute | | | | |
|------------------|----------------|-----------------|----------------|------|
| Time | Weight* (g) | Thickness mm | Hardness KP | Init |
| 1-36 PM | 1.068 | 2.66 | 2.68 | 3.8 |
| 1 Min. | 1.068 | 2.64 | 3.8 | 4.7 |
| 1-40 PM | 1.048 | 2.65 | 2.70 | 2.69 |
| 5 Min. | 1.048 | 2.69 | 2.9 | 3.8 |
| | | | 3.6 | 1.0 |

| Rear Exit Chute | | | | |
|-----------------|----------------|-----------------|----------------|------|
| Time | Weight* (g) | Thickness mm | Hardness KP | Init |
| 1 Min. | 1.060 | 2.70 | 2.72 | 2.74 |
| 1 Min. | 1.043 | 2.68 | 2.65 | 2.72 |
| 5 Min. | 1.043 | 2.65 | 2.72 | 3.4 |
| | | | 4.2 | 3.3 |
| | | | | 1.0 |

* Composite Weight of 10 Tablets

| Front Exit Chute | | | | | | | | | | |
|------------------|----------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet (mg) | | | | | | | | | |
| 1 Min. | 108 | 108 | 106 | 108 | 107 | 106 | 106 | 108 | 105 | 106 |
| 5 Min. | 104 | 108 | 105 | 104 | 107 | 105 | 105 | 108 | 109 | 106 |

| Rear Exit Chute | | | | | | | | | | |
|-----------------|----------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet (mg) | | | | | | | | | |
| 1 Min. | 107 | 104 | 102 | 104 | 103 | 106 | 107 | 104 | 106 | 108 |
| 5 Min. | 103 | 102 | 105 | 106 | 106 | 101 | 103 | 105 | 110 | 107 |

Comments:

Amide Pharmaceutical, Inc.

COMPRESSION DEPARTMENT

PROCESS VALIDATION

PRODUCT NAME: Digoxin Tablets 0.125mg (145)BATCH #: 5069ATABLET PRESS ID #: 66

| | Limit | Time |
|---------------|----------------|------|
| High RP | | |
| Low RP | N/A - AN 37-95 | |
| Maximum RP | | |
| Regular Speed | | |

| | RPM | Time |
|------------|--------------|--|
| High Speed | 28 | 12.12 min - 12.30 min ^{K.D. 3/7/95} |
| Low Speed | N/A AN 37-95 | — |

| | | | |
|----------|------|-------|--------|
| Done By: | K. D | Date: | 3/7/95 |
|----------|------|-------|--------|

PD101.1

Amide Pharmaceutical, Inc.

Process Validation

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COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 5069A

Date: 3/7/95

Tablet Press Id: 66

Hardness Tester Id: 251

Thickness Gauge Id: 646

Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : 1.0 - 6.0 KP

High Speed RPN 28

| Front Exit Chute | | | | |
|------------------|-------------|--------------|-------------|------|
| Time | Weight* (g) | Thickness mm | Hardness KP | Init |
| 12-11 PM | 1.061 | 2.58 | 2.63 | 4.4 |
| 1 Min. | 1.061 | 2.58 | 2.63 | 4.4 |
| 5 Min. | 1.061 | 2.58 | 2.63 | 4.4 |

| Rear Exit Chute | | | | |
|-----------------|-------------|--------------|-------------|------|
| Time | Weight* (g) | Thickness mm | Hardness KP | Init |
| 1 Min. | 1.063 | 2.61 | 2.63 | 4.4 |
| 5 Min. | 1.053 | 2.64 | 2.63 | 4.4 |

* Composite Weight of 10 Tablets

| Front Exit Chute | | | | |
|------------------|----------------------------|-----|-----|-----|
| Time | Weight of Each Tablet (mg) | | | |
| 1 Min. | 108 | 104 | 103 | 107 |
| 5 Min. | 107 | 106 | 103 | 106 |

| Rear Exit Chute | | | | |
|-----------------|----------------------------|-----|-----|-----|
| Time | Weight of Each Tablet (mg) | | | |
| 1 Min. | 106 | 108 | 106 | 104 |
| 5 Min. | 107 | 104 | 105 | 106 |

Comments:

Amide Pharmaceutical, Inc.

COMPRESSION DEPARTMENT

PROCESS VALIDATION

PRODUCT NAME: Digoxin Tablets 0.125 mg. (1/15)BATCH #: 5070ATABLET PRESS ID #: 66

| | Limit | Time |
|---------------|-------|------|
| High RP | N/A | |
| Low RP | | |
| Maximum RP | | |
| Regulat Speed | | |

| | RPM | Time |
|------------|---------------|----------|
| High Speed | 28 | 11.58 Am |
| Low Speed | N/A y 3/10/95 | |

| | | | |
|----------|------|-------|---------|
| Done By: | K. D | Date: | 3/10/95 |
|----------|------|-------|---------|

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Amide Pharmaceutical, Inc.

Process Validation

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COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 5070ADate: 3/10/95Tablet Press Id: 66 Hardness Tester Id: 251Thickness Gauge Id: 646 Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : 1.0 - 6.0 KP

High Speed 28 RPM

| Front Exit Chute | | | | | |
|------------------|----------------|-----------------|----------------|------|------|
| Time | Weight* (g) | Thickness mm | Hardness KP | | Init |
| 11:57 AM | 1.063 | 2.65 | 2.70 | 2.64 | 4.3 |
| 1 Min. | 1.063 | 2.65 | 2.70 | 2.64 | 4.3 |
| 5 Min. | 1.045 | 2.71 | 2.65 | 2.69 | 4.5 |

| Rear Exit Chute | | | | | |
|-----------------|----------------|-----------------|----------------|------|------|
| Time | Weight* (g) | Thickness mm | Hardness KP | | Init |
| 1 Min. | 1.045 | 2.60 | 2.58 | 2.57 | 4.0 |
| 5 Min. | 1.048 | 2.65 | 2.60 | 2.55 | 3.8 |

* Composite Weight of 10 Tablets

| Front Exit Chute | | | | | | | | | | |
|------------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | | |
| 1 Min. | 105 | 109 | 101 | 107 | 104 | 106 | 106 | 107 | 105 | 105 |
| 5 Min. | 104 | 106 | 111 | 105 | 104 | 106 | 107 | 105 | 106 | 106 |

| Rear Exit Chute | | | | | | | | | | |
|-----------------|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Time | Weight of Each Tablet(mg) | | | | | | | | | |
| 1 Min. | 116 | 104 | 102 | 102 | 105 | 106 | 102 | 105 | 103 | 105 |
| 5 Min. | 104 | 105 | 106 | 105 | 106 | 102 | 104 | 104 | 105 | 105 |

Comments:

<PD187.1>